**THE UNITED STATES PATENT AND TRADEMARK OFFICE**
**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| Appellant(s): | Petermann, et al. |
| Appl. No.: | 10/539,092 |
| Conf. No.: | 9222 |
| Filed: | June 15, 2005 |
| Title: | CHEMICALLY ACIDIFIED FORMULA |
| Art Unit: | 1794 |
| Examiner: | Dees, Nikki H. |
| Docket No.: | 112701-626 |

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**APPELLANTS' APPEAL BRIEF**

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on April 13, 2009. This Appeal is taken from the Final Rejection in the Office Action dated April 2, 2009.

## I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec S.A.

## II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignees of this patent application do not know of any prior or pending appeals, interferences or judicial proceedings that may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

## III. STATUS OF CLAIMS

Claims 1-2, 5-11 and 13 are pending in this application. Claims 3-4 and 12 were previously canceled. Claims 1-2, 5-11 and 13 stand rejected. Therefore, Claims 1-2, 5-11 and 13 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

## IV. STATUS OF AMENDMENTS

A non-final Office Action was mailed on November 20, 2008. Appellants responded to the non-final Office Action on February 10, 2009 amending Claims 1, 5, 7, 10 and 11 and canceling Claims 3 and 12 to overcome the objection, 35 U.S.C. §112 rejection and obviousness rejections set forth in the non-final Office Action. A final Office Action was mailed on April 2, 2009. In the final Office Action, the amendments were entered, and the objection and the 35 U.S.C. §112 rejection were withdrawn. The final Office Action also maintained the obviousness rejections. Appellants filed a Notice of Appeal on April 13, 2009. A copy of the non-final Office Action and final Office Action are attached as Exhibits A and B, respectively, in the Evidence Appendix.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the claimed subject matter by way of reference to the specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 1 is directed to a nutritional infant formula (page 4, line 23 to page 5, line 9) comprising a protein source (page 5, line 19; page 9, lines 9-17; page 10, lines 4-26), a carbohydrate source (page 5, line 19; page 11, lines 1-15) and a lipid source (page 9, lines 7-8; page 11, lines 16-25), the nutritional formula having a pH, in its liquid state (page 31, lines 20-26), in the range of 3.5 to 6 (page 5, lines 13-16), the formula comprising lactic acid (page 5, lines 13-16) and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid (page 5, lines 13-16; page 6, lines 3-5 and lines 13-14), the formula is directly acidified (page 5, lines 10-16; page 6, lines 15-18; page 16, lines 1-26).

Independent Claim 7 is directed to a method of preparing a nutritional infant formula (page 4, line 23 to page 5, line 9) comprising the steps of hydrating at least one of a protein source and a carbohydrate source (page 5, lines 17-20), directly acidifying (page 6, lines 15-18) the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained (page 5, lines 10-20; page 16, lines 1-26) and at least 70% of the lactic acid is present as L-(+) lactic acid (page 5, lines 10-16; page 6, lines 3-5 and lines 13-14).

Independent Claim 10 is directed to a method of preparing acidified nutritional infant formulas (page 4, line 23 to page 5, line 9) comprising the step of directly acidifying the nutritional formula (page 6, lines 15-18; page 16, lines 1-26) by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid (page 5, lines 23-24 and lines 13-14; page 8, lines 6-8).

Independent Claim 11 is directed to a method of preventing growth of pathogens in infant nutritional formulas (page 4, line 23 to page 5, line 9) comprising the step of directly acidifying the nutritional formula (page 6, lines 15-18; page 16, lines 1-26) by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid (page 5, lines 23-24 and lines 13-14; page 8, lines 6-8).

Although specification citations are given in accordance with 37 C.F.R. §1.192(c), these reference numerals and citations are merely examples of support in the specification for the

terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology in accordance with Rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-2, 5-11 and 13 are rejected to under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,475,539 to DeWille, et al. ("*DeWille*") in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) ("*PURAC*"). Copies of *DeWille* and *PURAC* are attached hereto as Exhibits C and D, respectively, in the Evidence Appendix.

2. Claims 1 and 5-6 rejected to under 35 U.S.C. §103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) ("*Schwartz*") in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) ("*WHO*") with additional evidence provided by Wong, et al. (Wong, Nobel P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag) ("*Wong*"). Copies of *Schwartz*, *WHO* and *Wong* are attached hereto as Exhibits E, F and G, respectively, in the Evidence Appendix.

3. Claims 1 and 5-11 rejected to under 35 U.S.C. §103(a) as being unpatentable over *Schwartz* in view of *PURAC* with additional evidence provided by *Wong*.

4. Claims 1 and 5-11 rejected to under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,212,893 to Takahata ("*Takahata*") in view of *WHO* with additional evidence provided by *Wong*. A copy of *Takahata* is attached hereto as Exhibit H in the Evidence Appendix.

## VII. ARGUMENT

A. LEGAL STANDARDS

Obviousness under 35 U.S.C. §103

The Federal Circuit has held that the legal basis for a determination of obviousness under 35 U.S.C. § 103 is:

> whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made…The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior art and the claimed invention; and (3) the level of ordinary skill in the art…Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness…Thus, each obviousness determination rests on its own facts.

*In re Mayne*, 41 U.S.P.Q. 2d 1451, 1453 (Fed. Cir. 1997).

In making this determination, the Examiner has the initial burden of proving a *prima facie* case of obviousness. *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q. 2d 1955, 1956 (Fed. Cir. 1993). This burden may only be overcome "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings." *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q. 2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Moreover, the Examiner must provide explicit reasons why the claimed invention is obvious in view of the prior art. The Supreme Court has emphasized that when formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR v. Teleflex*, 127 S. Ct. 1727 (2007).

Of course, references must be considered as a whole and those portions teaching against or away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). "A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged

from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant." *Monarch Knitting Mach. Corp. v. Fukuhara Indus. Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998) (quoting *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994)).

B. THE CLAIMED INVENTION

There are four independent claims on appeal: Claims 1, 7 and 10-11. Independent Claim 1 is generally directed to a nutritional infant formula comprising a protein source, a carbohydrate source and a lipid source. The nutritional formula has a pH, in its liquid state, in the range of 3.5 to 6. The formula further comprises lactic acid, and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid. The formula is directly acidified.

Independent Claim 7 is generally directed to a method of preparing a nutritional infant formula comprising the steps of hydrating at least one of a protein source and a carbohydrate source, directly acidifying the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained and at least 70% of the lactic acid is present as L-(+) lactic acid.

Independent Claim 10 is generally directed to a method of preparing acidified nutritional infant formulas comprising the step of directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid.

Independent Claim 11 is generally directed to a method of preventing growth of pathogens in infant nutritional formulas comprising the step of directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid.

Appellants have surprisingly found that preparing nutritional formulas based on direct acidification with L(+)-lactic acid can provide nutritional formulas that have bacteriostatic activity while still being nutritionally safe for infants. See specification, Example 1. The term "directly acidified" refers to the fact that the lactic acid is directly added to the nutritional formula during its preparation. See specification, page 6, lines 15-18. The acidity of L(+)-lactic acid is not obtained by a fermentation process of the formula, wherein lactic acid bacteria

produce the lactic acid and the formula is thus continuously acidified over a time span of usually 2-10 hours.

C. THE REJECTION OF CLAIMS 1-2, 5-11 AND 13 UNDER 35 U.S.C. §103(A) TO *DEWILLE* AND *PURAC* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO CLAIMS 1-2, 5-11 AND 13

1. *DeWille* and *PURAC* alone or in combination fail to disclose or suggest the claimed invention

Independent Claim 1 recites, in part, a nutritional infant formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid. The formula is directly acidified by the L(+)-lactic acid. Independent Claim 7 recites, in part, a method of preparing a nutritional infant formula comprising directly acidifying the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained and at least 70% of the lactic acid is present as L-(+) lactic acid. Independent Claims 10 and 11 recite, in part, a method comprising directly acidifying a nutritional infant formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid. In contrast, Appellants respectfully submit that *DeWille* and *PURAC* alone or in combination fail to disclose or suggest a number of elements of independent Claims 1, 7 and 10-11.

*DeWille* fails to disclose or suggest a nutritional infant formula directly acidified by L(+)-lactic acid as required by independent Claims 1, 7 and 10-11. *DeWille* also fails to disclose or suggest a nutritional infant formula wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid as required by independent Claims 1 and 7. In addition, *DeWille* fails to disclose or suggest directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid as required by independent Claims 10-11. Though *DeWille* discloses a lactic acid, *DeWille* teaches the general use of food grade acid and merely mentions lactic acid as one of among at least 8 types of food

grade acid. Moreover, *DeWille* fails to teach, suggest, or even mention the specific use of L(+)-lactic acid as required by the claims. The Examiner admits the same. See final Office Action, paragraph 8. The Examiner further admits that *DeWille* is silent as to the formula being an infant formula. *Id.*

*PURAC* fails to disclose or suggest a nutritional infant formula directly acidified by L(+)-lactic acid as required by independent Claims 1, 7 and 10-11. *PURAC* also fails to disclose or suggest a nutritional infant formula wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid as required by independent Claims 1 and 7. In addition, *PURAC* fails to disclose or suggest directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid as required by independent Claims 10-11. *PURAC* generally teaches natural lactic acid in several forms, concentrations and qualities. *PURAC* fails to provide any suggestion or guidance for using the lactic acid in compositions such as a nutritional infant formula and fails to teach any methods of making such compositions by directly acidifying the formula with the lactic acid. In fact, *PURAC* is only a catalogue listing natural lactic acid and lactate forms.

For at least the reasons discussed above, *DeWille* and *PURAC* alone or in combination fail to disclose or suggest: 1) a nutritional infant formula directly acidified by L(+)-lactic acid, 2) the specific proportion of L(+)-lactic acid and 3) directly acidifying a nutritional infant formula using L(+)-lactic acid, as required by independent Claims 1, 7 and 10-11. Accordingly, Appellants respectfully submit that Claims 1, 7 and 10-11, along with the claims that depend from Claims 1, 7 and 10-11, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

2. The skilled artisan would have no reason to combine *DeWille* and *PURAC* to arrive at the claimed invention

Appellants respectfully submit that the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight. Moreover, Appellants respectfully submit that the Examiner is using Appellants' patent application as a road map for creating hindsight obviousness and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of *DeWille* and *PURAC*.

*DeWille* generally discloses the use of general lactic acid in an enteral nutritional formulation. However, *DeWille* fails to teach, suggest, or even mention specific use of L(+)-lactic acid or that at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid. Simply disclosing the use of lactic acid does not make it obvious to one skilled in the art that this disclosure refers to L(+)-lactic acid or has a specific reason to use L(+)-lactic acid. Moreover, beside L(+)-lactic acid, the skilled artisan understands that general "lactic acid" could refer, for example, to a number of other possibilities such as a racemic of lactic acid and another acid, potassium lactate, sodium lactate, D(-)-lactate, DL-lactic acid, or D(-)lactic acid.

The Examiner asserts, however, that it would have been obvious to use L(+) lactic acid, cited in the product data sheet of *PURAC*, to acidify the formula in *DeWille* and that Appellants are doing no more than using a known compound for its intended use in order to provide a predictable result of acidifying a foodstuff. See final Office Action, paragraph 10. Appellants respectfully disagree. Simply citing a product data sheet (*PURAC*) that publishes information for two of many different kinds "lactic acid" in no way remedies the deficiency of *DeWille* and provides no specific guidance to use L(+)-lactic acid to directly acidify a nutritional infant formula in accordance with the present claims. Just disclosing analytical information regarding two lactic acid ingredients does not provide one skilled in the art any reason to use the specific lactic acid disclosed in *PURAC* as the general lactic acid taught in *DeWille* in the absence of hindsight.

Nothing in *PURAC* teaches or suggests that the lactic acid taught therein is desirable or safe for use in infant formulations in accordance with the present claims. As a result, the skilled artisan would have no reason to specifically choose L(+)-lactic acid from PURAC to add to the nutritional formulation of *DeWille*. Nevertheless, even *DeWille* is not concerned with infant formulas as it teaches components that would not be acceptable in an infant formula such as the stabilizing system comprising high methoxy pectin, which is an essential feature of *DeWille*.

Appellants respectfully submit that it is only with a hindsight reconstruction of Appellants' claimed invention that the Examiner is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. However, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37

USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988). In this regard, Appellants respectfully submit that there is absolutely no guidance in the cited reference for one of skill in the art to *DeWille* and *PURAC* as Appellants have done.

The Examiner assumes that it would have been within the ordinary skill of the artisan at the time the claimed invention was made because the references relied upon allegedly teach that all aspects of the claimed invention were individually known in the art. However, this conclusory statement is not sufficient to establish a *prima facie* case of obviousness without some objective reason to utilize the teachings of the references to arrive at the invention. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness by the Examiner. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

In sum, the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight. Moreover, *DeWille* and *PURAC* fail to even recognize the advantages, benefits and/or properties of a nutritional infant formulation directly acidified by L(+)-lactic acid in accordance with the present claims. Instead, Appellants respectfully submit that the Examiner is improperly using Appellants' patent application as a road map for creating hindsight obviousness. Accordingly, Appellants respectfully submit that Claims 1, 7 and 10-11, along with the claims that depend from Claims 1, 7 and 10-11, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

D. THE REJECTION OF CLAIMS 1 AND 5-6 UNDER 35 U.S.C. §103(A) TO *SCHWARTZ, WHO* AND *WONG* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO CLAIMS 1 AND 5-6

1. *Schwartz, WHO* and *Wong* alone or in combination fail to disclose or suggest the claimed invention

Independent Claim 1 recites, in part, a nutritional infant formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the formula directly acidified. In contrast, Appellants respectfully submit that *Schwartz*, *WHO* and *Wong* alone or in combination fail to disclose or suggest a number of elements of independent Claim 1.

*Schwartz*, *WHO* and *Wong* fail to disclose or suggest a nutritional infant formula directly acidified with L(+)-lactic acid as required by independent Claim 1. *Schwartz*, *WHO* and *Wong* also fail to disclose or suggest a nutritional infant formula wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid as required by independent Claim 1.

*Schwartz* is generally directed to the use of lactic acid milk with varying proportions of carbohydrates during infant feeding. The Examiner admits the that *Schwartz* fails to disclose or suggest L(+)-lactic acid. See final Office Action, paragraph 16. *WHO* fails to remedy the deficiency of *Schwartz* with regard to an L(+)-lactic acid because *WHO* fails to disclose or suggest directly acidifying an infant formula using L(+)-lactic acid. Moreover, *Wong* also fails to remedy this deficiency of *Schwartz* as the Examiner only relies on *Wong* for merely disclosing that proteins can comprise whey protein and casein. See final Office Action, paragraph 15. Finally, *Schwartz*, *WHO* and *Wong* all fail to recognize the benefits and advantages that directly acidifying a nutritional infant formula with L(+)-lactic acid has with respect to bacteriostatic activity.

For at least the reasons discussed above, *Schwartz*, *WHO* and *Wong* alone or in combination fail to disclose or suggest: 1) a nutritional infant formula directly acidified by L(+)-lactic acid, and 2) the specific proportion of L(+)-lactic acid, as required by independent Claim 1. Accordingly, Appellants respectfully submit that Claim 1, along with Claims 5-6 that depend from Claim 1, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

2. The skilled artisan would have no reason to combine *Schwartz*, *WHO* and *Wong* to arrive at the claimed invention

Appellants respectfully submit that the skilled artisan would not arrive at the claimed invention using the cited references in the absence of hindsight because the cited references are

entirely directed to compositions utilizing different nutritional ingredients for different intended purposes. Moreover, Appellants respectfully submit that the Examiner is using Appellants' patent application as a road map for creating hindsight obviousness and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of *Schwartz*, *WHO* and *Wong*.

*Schwartz* is generally directed to the use of lactic acid milk with varying proportions of carbohydrates during infant feeding but fails to specifically teach or suggest using L(+)-lactic acid to directly acidify the infant milk. *Wong* discloses proteins comprising whey protein and casein. The Examiner asserts that, in view of *WHO*, one of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in infant formula of *Schwartz* because *WHO* teaches away from DL lactic acid usage and therefore teaches away from the inclusion of D(-) lactic acid, not the L(+) lactic acid of the present claims. See final Office Action, paragraph 17.

Appellants respectfully disagree and submit that *WHO* teaches away from general DL lactic acid usage as a whole in nutritional infant formulas. DL-lactic acid, a racemic mixture of L(+) and D(-) lactic acid forms, was administered to infants. Neither L(+) nor D(-) lactic acid forms were individually administered. *WHO* mentions that infants had more difficulty metabolizing D(-) lactic acids than L(+) lactic acids based on urinary excretion. Although D(-) lactic acid may have been harder to metabolize than L(+)-lactic acid, no part of *WHO* teaches that infants can positively utilize L(+)-lactic acid alone or that L(+)-lactic acid should be favorably administered to infants. There is no evidence that *WHO* was referring specifically to D(-) lactic acid avoidance rather than L(+) lactic acid avoidance. Rather, *WHO* discloses that the urinary excretion of either form of lactic acid indicates that a young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in the diet. See *WHO*, page 4, lines 16-19. As a result, based on the negative results of the racemic DL lactic acid as a whole, *WHO* actually teaches away from using any type of lactic acid (whether in L(+) and D(-) lactic acid forms) in nutritional infant formulas.

In sum, the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight. Moreover, *Schwartz*, *WHO* and *Wong* fail to even recognize the advantages, benefits and/or properties of a nutritional infant formula directly acidified by L(+) lactic acid in accordance with the present claims. Instead, Appellants

respectfully submit that the Examiner is improperly using Appellants' patent application as a road map for creating hindsight obviousness. Accordingly, Appellants respectfully submit that Claim 1, along with Claims 5-6 that depend from Claim 1, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

E. THE REJECTION OF CLAIMS 1 AND 5-11 UNDER 35 U.S.C. §103(A) TO *SCHWARTZ, PURAC* AND *WONG* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO CLAIMS 1 AND 5-11

1. *Schwartz, PURAC* and *Wong* alone or in combination fail to disclose or suggest the claimed invention

Independent Claim 1 recites, in part, a nutritional infant formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the formula directly acidified. Independent Claim 7 recites, in part, a method of preparing a nutritional infant formula comprising directly acidifying the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained and at least 70% of the lactic acid is present as L-(+) lactic acid. Independent Claims 10 and 11 recite, in part, a method comprising directly acidifying a nutritional infant formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid. In contrast, Appellants respectfully submit that *Schwartz, PURAC* and *Wong* alone or in combination fail to disclose or suggest a number of elements of independent Claim 1.

*Schwartz, PURAC* and *Wong* fail to disclose or suggest a nutritional infant formula directly acidified by L(+)-lactic acid as required by independent Claims 1, 7 and 10-11. *Schwartz, PURAC* and *Wong* also fail to disclose or suggest a nutritional infant formula wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid as required by independent Claims 1 and 7. In addition, *Schwartz, PURAC* and *Wong* fail to disclose or suggest directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid as required by independent Claims 10-11.

The Examiner admits the that *Schwartz* fails to disclose or suggest L(+)-lactic acid. See final Office Action, paragraph 24. *Wong* is deficient as the Examiner only relies on *Wong* merely for disclosing that proteins comprise whey protein and casein. Finally, *PURAC* is also deficient because it fails to teach use of L(+) lactic acid in infant formulas. Moreover, *Schwartz*, *PURAC* and *Wong* all fail to recognize the benefits and advantages that directly acidifying a nutritional infant formula with L(+)-lactic acid has with respect to bacteriostatic activity.

For at least the reasons discussed above, *Schwartz*, *PURAC* and *Wong* alone or in combination fail to disclose or suggest: 1) a nutritional infant formula directly acidified by L(+)-lactic acid, 2) the specific proportion of L(+)-lactic acid and 3) directly acidifying a nutritional infant formula using L(+)-lactic acid, as required by independent Claims 1, 7 and 10-11. Accordingly, Appellants respectfully submit that Claims 1, 7 and 10-11, along with the claims that depend from Claims 1, 7 and 10-11, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

2. The skilled artisan would have no reason to combine *Schwartz*, *PURAC* and *Wong* to arrive at the claimed invention

Appellants respectfully submit that the skilled artisan would not arrive at the claimed invention using the cited references in the absence of hindsight because the cited references are entirely directed to compositions utilizing different nutritional ingredients for different intended purposes. Moreover, Appellants respectfully submit that the Examiner is using Appellants' patent application as a road map for creating hindsight obviousness and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of *Schwartz*, *PURAC* and *Wong*.

*Schwartz* is generally directed to the use of lactic acid milk with varying proportions of carbohydrates during infant feeding but fails to specifically teach or suggest using L(+)-lactic acid to directly acidify the infant milk. *Wong* discloses proteins comprising whey protein and casein.

*PURAC* fails to disclose, suggest or even mention application of its product to infant formulas. In addition, simply citing a product data sheet (*PURAC*) that publishes information for two of many different kinds "lactic acid" in no way remedies the deficiency of *Schwartz* and

provides no specific guidance to use L(+)-lactic acid to directly acidify a nutritional infant formula in accordance with the present claims. Just disclosing analytical information regarding two lactic acid ingredients does not provide one skilled in the art any reason to use the specific lactic acid disclosed in *PURAC* as the general lactic acid taught in *Schwartz* in the absence of hindsight.

In sum, the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight. Moreover, *Schwartz*, *PURAC* and *Wong* fail to even recognize the advantages, benefits and/or properties of a nutritional infant formula directly acidified by L(+)-lactic acid in accordance with the present claims. Instead, Appellants respectfully submit that the Examiner is improperly using Appellants' patent application as a road map for creating hindsight obviousness. Accordingly, Appellants respectfully submit that Claims 1, 7 and 10-11, along with the claims that depend from Claims 1, 7 and 10-11, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

F. THE REJECTION OF CLAIMS 1 AND 5-11 UNDER 35 U.S.C. §103(A) TO *TAKAHATA*, *WHO* AND *WONG* SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A *PRIMA FACIE* CASE OF OBVIOUSNESS WITH RESPECT TO CLAIMS 1-10 AND 25-30

1. *Takahata*, *WHO* and *Wong* alone or in combination fail to disclose or suggest the claimed invention

Independent Claim 1 recites, in part, a nutritional infant formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the formula directly acidified. Independent Claim 7 recites, in part, a method of preparing a nutritional infant formula comprising directly acidifying the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained and at least 70% of the lactic acid is present as L-(+) lactic acid. Independent Claims 10 and 11 recite, in part, a method comprising directly acidifying a nutritional infant formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid. In

contrast, Appellants respectfully submit that *Takahata*, *WHO* and *Wong* alone or in combination fail to disclose or suggest a number of elements of independent Claims 1, 7 and 10-11.

*Takahata*, *WHO* and *Wong* fail to disclose or suggest a nutritional infant formula directly acidified by L(+)-lactic acid as required by independent Claims 1, 7 and 10-11. *Takahata*, *WHO* and *Wong* also fail to disclose or suggest a nutritional infant formula wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid as required by independent Claims 1 and 7. In addition, *Takahata*, *WHO* and *Wong* fail to disclose or suggest directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid as required by independent Claims 10-11.

*Takahata* is generally directed to an acidified whole milk beverage that uses an acidifying agent such as fruit juice or organic acid. Nevertheless, *Takahata* fails to disclose or suggest any use of L(+)-lactic acid as required by the present claims. The Examiner admits the same. See final Office Action, paragraph 31.

As stated previously, *WHO* fails to remedy this deficiency with regard to L(+)-lactic acid because (a) *WHO* fails to disclose or suggest an infant formula directly acidified by L(+)-lactic acid and (b) *WHO* actually teaches away from using lactic acid in nutritional formulas. Moreover, *Wong* fails to remedy this deficiency as the Examiner only relies on *Wong* for merely disclosing that proteins can comprise whey protein and casein. In addition, *Takahata*, *WHO* and *Wong* all fail to recognize the benefits and advantages that directly acidifying a nutritional infant formula with L(+)-lactic acid has with respect to bacteriostatic activity.

For at least the reasons discussed above *Takahata*, *WHO* and *Wong* alone or in combination fail to disclose or suggest: 1) a nutritional infant formula directly acidified by L(+)-lactic acid, 2) the specific proportion of L(+)-lactic acid and 3) directly acidifying a nutritional infant formula using L(+)-lactic acid, as required by independent Claims 1, 7 and 10-11. Accordingly, Appellants respectfully submit that Claims 1, 7 and 10-11, along with the claims that depend from Claims 1, 7 and 10-11, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

2. The skilled artisan would have no reason to combine *Takahata*, *WHO* and *Wong* to arrive at the claimed invention

Appellants respectfully submit that the skilled artisan would not arrive at the claimed invention using the cited references in the absence of hindsight because the cited references are entirely directed to compositions utilizing different nutritional ingredients for different intended purposes. Moreover, Appellants respectfully submit that the Examiner is using Appellants' patent application as a road map for creating hindsight obviousness and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of *Takahata*, *WHO* and *Wong*.

*WHO* teaches administering DL-lactic acid to babies and does not teach direct acidification an infant formula with a specific L(+)-lactic acid. See *WHO*, page 5. DL-lactic acid is a racemic mixture of L(+) and D(-) lactic acid forms. Neither L(+) nor D(-) lactic acid forms were individually administered. Rather, these individual lactic acids forms were only measured when excreted in urine. Because the experiments in *WHO* show that infants had difficulty utilizing DL and D(-) lactic acids, infants inherently had difficulty utilizing both L(+) and D(-) lactic acid forms. See *WHO*, page 4, lines 16-19. Although D(-) lactic acid may have been harder to metabolize than L(+)-lactic acid, no part of *WHO* teaches that infants can positively utilize L(+)-lactic acid alone. Instead, based on the negative results of the racemic DL lactic acid as a whole, *WHO* actually teaches away from using any type of lactic acid (in L(+) and D(-) lactic acid forms) in nutritional infant formulas.

In sum, the skilled artisan would have no reason to arrive at the claimed invention using the cited references in the absence of hindsight. Moreover, *Takahata*, *WHO* and *Wong* fail to even recognize the advantages, benefits and/or properties of a nutritional infant formula directly acidified by L(+)-lactic acid in accordance with the present claims. Instead, Appellants respectfully submit that the Examiner is improperly using Appellants' patent application as a road map for creating hindsight obviousness. Accordingly, Appellants respectfully submit that Claims 1, 7 and 10-11, along with the claims that depend from Claims 1, 7 and 10-11, are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

## VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103 with respect to the rejection of Claims 1-2, 5-11 and 13. Accordingly, Appellants respectfully submit that the obviousness rejections are erroneous in law and in fact and should therefore be reversed by this Board.

A check in the amount of $510 is submitted herewith to cover the cost of the Appeal Brief. The Director is authorized to charge any additional fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-626 on the account statement.

Respectfully submitted,

K&L GATES LLP

BY 

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Dated: June 15, 2009

## CLAIMS APPENDIX

## PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/539,092

1. A nutritional infant formula comprising a protein source, a carbohydrate source and a lipid source, the nutritional formula having a pH, in its liquid state, in the range of 3.5 to 6, the formula comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the formula is directly acidified.

2. The nutritional formula according to Claim 1, wherein the nutritional formula is in a powder form.

5. The nutritional formula according to Claim 1 comprising a protein source selected from the group consisting of whole or skimmed milk powder, casein, whey protein, soy protein, rice protein, carob seed protein, germ flour protein, and mixtures thereof.

6. The nutritional formula according to Claim 5, wherein the casein and whey protein is intact or not hydrolysed.

7. A method of preparing a nutritional infant formula comprising the steps of

hydrating at least one of a protein source and a carbohydrate source,

directly acidifying the hydrated carbohydrate source and/or the hydrated protein source by adding diluted L-(+) lactic acid until a pH of about 3.5 – 6 is obtained and at least 70% of the lactic acid is present as L-(+) lactic acid.

8. The method according to Claim 7, comprising the further step of adding a lipid source.

9. The method according to Claim 8, wherein the step of adding a lipid source is performed before adding L-(+) lactic acid.

10. A method of preparing acidified nutritional infant formulas comprising the step of directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid.

11. A method of preventing growth of pathogens in infant nutritional formulas comprising the step of directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid.

13. The nutritional formula according to claim 1, wherein the nutritional formula comprises 0.5-3.5% by weight L(+)-lactic acid, based on the dry weight of the nutritional formula.

## EVIDENCE APPENDIX

EXHIBIT A: Non-final Office Action dated November 20, 2008

EXHIBIT B: Final Office Action dated April 2, 2009

EXHIBIT C: U.S. Patent No. 6,475,539 to DeWille, et al. ("*DeWille*"), cited by the Examiner in the Office Action dated April 2, 2009

EXHIBIT D: PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) ("*PURAC*"), cited by the Examiner in the Office Action dated April 2, 2009

EXHIBIT E: Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) ("*Schwartz*"), cited by the Examiner in the Office Action dated April 2, 2009

EXHIBIT F: WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) ("*WHO*"), cited by the Examiner in the Office Action dated April 2, 2009

EXHIBIT G: Wong, et al. (Wong, Nobel P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag) ("*Wong*"), cited by the Examiner in the Office Action dated April 2, 2009

EXHIBIT H: U.S. Patent No. 4,212,893 to Takahata ("*Takahata*"), cited by the Examiner in the Office Action dated April 2, 2009

## RELATED PROCEEDINGS APPENDIX

None

# EXHIBIT A

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/539,092 | 06/15/2005 | Robert Petermann | 112701-626 | 9222 |

29157 7590 11/20/2008

BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

| EXAMINER | |
|---|---|
| DEES, NIKKI H | |
| ART UNIT | PAPER NUMBER |
| 1794 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 11/20/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/539,092 | PETERMANN ET AL. | |
| | Examiner | Art Unit | |
| | Nikki H. Dees | 1794 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3 and 5-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 19, 2008, has been entered.

2. Claims 1-3 and 5-13 are currently pending in the application. Claim 4 has been cancelled. The previous 112 rejection of claim 13 has been withdrawn in view of Applicant's amendment to claim 13. The previous 103 rejection of claims 1, 2, and 7-13 over Mazer in view of WHO has been withdrawn in view of Applicant's amendment to claim 1.

### *Claim Objections*

3. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 limits the source

of claim 1 to a source selected form protein, carbohydrate, and lipid. Amended claim 1 requires all of a protein source, a carbohydrate source and a lipid source. As all of the limitations of claim 12 are required in claim 1, claim 12 is not considered further limiting.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 5 is dependent upon claim 4, which has been cancelled. For purposes of examination, claim 5 will be interpreted as being dependent upon claim 1.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (6,475,539) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html).

9. DeWille et al. teach a nutritional formula that comprises a protein source, a carbohydrate source, a lipid source, and lactic acid. The formula in its liquid state has a pH of 3.0-4.6 (col. 6 lines 13-47). The solution may be directly acidified. That is, the pH of the solution may be adjusted by the addition of the acid, not fermentation (col. 15 lines 9-34). The nutritional formula may be provided as a ready-to-feed form, concentrate, or powder (col. 10 lines 26-30). Protein sources taught for use in the invention include whey protein and casein. The whey protein is used as a concentrate or isolate, which, as an essentially undenatured protein, is considered to be intact (col. 11 lines 36-50).

10. Regarding claims 7-9, DeWille et al. teach that the formula is prepared by first forming a protein/carbohydrate/oil mixture that is then acidified with an edible acid (col. 20 lines 1-9).

11. Regarding claims 10 and 11, the statements of intended use for the methods are not considered to patentably distinguish over the prior art. DeWille et al. teach preparing acidified nutritional formula by directly adding lactic acid to the nutritional formula (col. 15 lines 9-34). Further, low pH in foodstuffs is known to inhibit microbial growth (col. 6 lines 8-10).

12. Regarding claim 13, the amount of acid in the invention encompasses the range of percentages as claimed by applicants when calculated on a dry weight basis using

claims 1 and 7 of DeWille et al. As DeWille et al. teach lactic acid for use in their invention, and their formula has a pH in the range overlapping the range claimed by Applicant's, it would have been expected that the amount of lactic acid needed to provide a pH as claimed by DeWille et al. would fall within the range claimed by Applicants.

13. DeWille et al. are silent as to their invention comprising L(+) lactic acid and to the formula being an infant formula.

14. Purac teaches the availability of edible L(+) lactic acid solution. The FCC products are indicated to be foodsafe.

15. One of ordinary skill in the art at the time the invention was made, desiring to acidify the invention of DeWille et al. with lactic acid, would have found it obvious to use L(+) lactic acid to provide the acidification. L(+) lactic acid was known in the art for addition to foodstuffs, and lactic acid is specifically taught as an acidulent in the nutritional formula of DeWille et al. Applicant is doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff. Therefore, the combination of DeWille et al. the PURAC products FCC 50, 80 or 88 would have been obvious to one of ordinary skill in the art at the time the invention was made.

16. Regarding the invention of DeWille et al. being an infant formula, one of ordinary skill in the art at the time the invention was made, wishing to provide a complete nutritional product for infants rather than children 13 months and older as taught by DeWille et al. (col. 10 lines 55-59) would have been able to modify the nutritional profile

of DeWille et al. in order to provide a nutritional formula that met the nutritional needs of infants. One of ordinary skill, working from the teachings of DeWille et al., would have found it obvious to provide a shelf stable product that met the nutritional needs of infants. These modifications would not have required undue experimentation, and would have been expected to result in an appropriately acidified infant nutritional formula.

17. Claims 1, 3-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

18. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

19. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

20. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

21. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

22. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) – lactic acid as taught by the WHO in order to result in an infant formula with higher acidity for improved digestion.

24. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

25. Claims 1, 3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

26. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

27. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

28. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

29. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

30. Purac teaches edible L(+) lactic acid that is in compliance with all major food codices.

31. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) lactic acid as taught by Purac to result in an infant formula with higher acidity for improved digestion. Applicant is utilizing a known compound, L(+) lactic acid, for its intended use as a food acidulent in order to provide the obvious combination of an acidified infant nutritional formula. This combination is further considered to obvious as there would be no undue experimentation required to utilize the L(+) lactic acid where the addition of lactic acid is specifically taught by Schwartz.

32. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the

pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

33. Claims 1, 3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata (4,212,893) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

34. Takahata teaches an acidified whole milk beverage comprising whole milk and an organic acid (Abstract). Organic acids taught include lactic acid (col. 2 lines 32-36). The final pH of the beverage taught is within the range of 2.5 to 4.5 (col. 2 lines 25-27).

35. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

36. Takahata is silent as to the enantiomeric ratio of lactic acid present in his composition.

37. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

38. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized L (+) – lactic acid in the beverage taught by

Takahata in order to result in a beverage that may be marketed to the widest possible audience, including infants.

***Response to Arguments***

39. Applicant's arguments filed September 19, 2008, have been fully considered but they are not persuasive.

40. The 103 rejection over Mazer et al. in view of WHO has been withdrawn in view of Applicant's amendment to claim 1. Mazer et al. do not teach their nutritional formula comprising a protein source, lipid source and carbohydrate source. A new ground of rejection has been presented *supra* addressing Applicant's amended claim 1.

41. With regard to the 103 rejection of claims 1, 3-6 and 12 over Schwartz in view of WHO, Applicant argues that the combination of references does not teach all of the elements of the rejected claims (Remarks, p. 7). Applicant further argues (Remarks, p. 8) that WHO fails to teach the use of L(+) lactic acid in formula and WHO teaches away from using L(+).

42. The WHO teaches that D-(-) and DL -lactic acid are not appropriate for use in infant formulas. One of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in the infant formula where the direct addition of lactic acid is specifically taught and that the teaching away from the use of DL lactic acid is to

avoid the inclusion of D(-) lactic acid, not the L(+) that is also present in the mixture. L(+) acid is known to be present in mammalian metabolism (WHO, p. 1), providing further motivation to use L(+) lactic acid in foodstuffs intended for human consumption. One of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature and could have utilized the L(+) lactic acid without any undue experimentation to result in the directly acidified formula as taught by Schwartz.

43. With regard to the 103 rejection of claims 1, 3-6 and 12 over Takahata in view of WHO, Applicant again argues that the combination of references does not teach all of the elements of the rejected claims (Remarks, p. 8).

44. The WHO teaches that D-(-) and DL -lactic acid are not appropriate for use in infant formulas. One of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in the infant formula and that the teaching away from the use of DL lactic acid is to avoid the inclusion of D(-) lactic acid, not the L(+) that is also present in the mixture. L(+) acid is known to be present in mammalian metabolism (WHO, p. 1), providing further motivation to use L(+) lactic acid in foodstuffs intended for human consumption. One of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature and could have utilized the L(+) lactic acid without any undue experimentation to result in the acidified formula as taught by Takahata.

***Conclusion***

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alm (Alm, L. 1982. "Effect of Fermentation on L(+) and D(-) Lactic Acid in Milk" J. Dairy Sci. Vol. 65. pp. 515-520). Column 2 second full paragraph states "Restricted consumption of products containing high D(-) lactic acid is recommended, and in infant nutrition products containing D(-) or DL mixture should be avoided."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees
Examiner
Art Unit 1794

/Carol Chaney/
Supervisory Patent Examiner, Art Unit 1794

# EXHIBIT B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
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| 10/539,092 | 06/15/2005 | Robert Petermann | 112701-626 | 9222 |

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K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

| EXAMINER | |
|---|---|
| DEES, NIKKI H | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1794 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 04/02/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/539,092 | PETERMANN ET AL. | |
| | Examiner | Art Unit | |
| | Nikki H. Dees | 1794 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,5-11 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

1. The Amendment filed February 10, 2009, has been entered. Claims 1, 2, 5-11, and 13 are currently pending in the application. Claims 3, 4, and 12 have been cancelled. The previous objection to claim 12 is withdrawn in view of the cancellation of claim 12. The previous 112 rejection of claim 5 is withdrawn in view of the amendment to claim 5.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 2, 5-11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (6,475,539) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html).

4. DeWille et al. teach a nutritional formula that comprises a protein source, a carbohydrate source, a lipid source, and lactic acid. The formula in its liquid state has a pH of 3.0-4.6 (col. 6 lines 13-47). The solution may be directly acidified. That is, the pH of the solution may be adjusted by the addition of the acid, not fermentation (col. 15 lines 9-34). The nutritional formula may be provided as a ready-to-feed form,

concentrate, or powder (col. 10 lines 26-30). Protein sources taught for use in the invention include whey protein and casein. The whey protein is used as a concentrate or isolate, which, as an essentially undenatured protein, is considered to be intact (col. 11 lines 36-50).

5. Regarding claims 7-9, DeWille et al. teach that the formula is prepared by first forming a protein/carbohydrate/oil mixture that is then acidified with an edible acid (col. 20 lines 1-9).

6. Regarding claims 10 and 11, the statements of intended use for the methods are not considered to patentably distinguish over the prior art. DeWille et al. teach preparing acidified nutritional formula by directly adding lactic acid to the nutritional formula (col. 15 lines 9-34). Further, low pH in foodstuffs is known to inhibit microbial growth (col. 6 lines 8-10).

7. Regarding claim 13, the amount of acid in the invention encompasses the range of percentages as claimed by applicants when calculated on a dry weight basis using claims 1 and 7 of DeWille et al. As DeWille et al. teach lactic acid for use in their invention, and their formula has a pH in the range overlapping the range claimed by Applicant's, it would have been expected that the amount of lactic acid needed to provide a pH as claimed by DeWille et al. would fall within the range claimed by Applicants.

8. DeWille et al. are silent as to their invention comprising L(+) lactic acid and to the formula being an infant formula.

9. Purac teaches the availability of edible L(+) lactic acid solution. The FCC products are indicated to be foodsafe.

10. One of ordinary skill in the art at the time the invention was made, desiring to acidify the invention of DeWille et al. with lactic acid, would have found it obvious to use L(+) lactic acid to provide the acidification. L(+) lactic acid was known in the art for addition to foodstuffs, and lactic acid is specifically taught as an acidulent in the nutritional formula of DeWille et al. Applicant is doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff. Therefore, the combination of DeWille et al. the PURAC products FCC 50, 80 or 88 would have been obvious to one of ordinary skill in the art at the time the invention was made.

11. Regarding the invention of DeWille et al. being an infant formula, one of ordinary skill in the art at the time the invention was made, wishing to provide a complete nutritional product for infants rather than children 13 months and older as taught by DeWille et al. (col. 10 lines 55-59) would have been able to modify the nutritional profile of DeWille et al. in order to provide a nutritional formula that met the nutritional needs of infants. One of ordinary skill, working from the teachings of DeWille et al., would have found it obvious to provide a shelf stable product that met the nutritional needs of infants. These modifications would not have required undue experimentation, and would have been expected to result in an appropriately acidified infant nutritional formula.

12. Claims 1, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

13. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

14. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

15. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

16. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

17. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding

infants as taught by Schwartz with L (+) – lactic acid as taught by the WHO in order to result in an infant formula with higher acidity for improved digestion.

19. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

20. Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

21. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

22. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

23. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

24. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

25. Purac teaches edible L(+) lactic acid that is in compliance with all major food codices.

26. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) lactic acid as taught by Purac to result in an infant formula with higher acidity for improved digestion. Applicant is utilizing a known compound, L(+) lactic acid, for its intended use as a food acidulent in order to provide the obvious combination of an acidified infant nutritional formula. This combination is further considered to obvious as there would be no undue experimentation required to utilize the L(+) lactic acid where the addition of lactic acid is specifically taught by Schwartz.

27. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

28. Claims 1 and 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata (4,212,893) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

29. Takahata teaches an acidified whole milk beverage comprising whole milk and an organic acid (Abstract). Organic acids taught include lactic acid (col. 2 lines 32-36). The final pH of the beverage taught is within the range of 2.5 to 4.5 (col. 2 lines 25-27).

30. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

31. Takahata is silent as to the enantiomeric ratio of lactic acid present in his composition.

32. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized L (+) – lactic acid in the beverage taught by Takahata in order to result in a beverage that may be marketed to the widest possible audience, including infants.

***Response to Arguments***

34. Applicant's arguments filed February 10, 2009, have been fully considered but they are not persuasive.

35. With regard to the 103 rejection over DeWille in view of PURAC, Applicant argues that the disclosure of product literature from PURAC does not provide specific reason to choose the product as claimed (Remarks, p. 5)

36. DeWille discloses an invention comprising lactic acid, as detailed above. The specific lactic acid for use in the invention is not detailed. The PURAC product is a commercially available L(+)-lactic acid that is taught to be safe for use in foodstuffs. One of ordinary skill, when producing a food formulation requiring lactic acid, would have found it obvious to have selected a known, commercially available, food-safe lactic acid for use in the invention.

37. Applicant further argues the combination does not teach a formula that is safe for infants, as required by the present claims (Remarks, p. 5).

38. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., infant safety) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

39. The rejection of claims 1, 2, 5-11 and 13 over DeWille in view of PURAC meets the limitations of the rejected claims, including the may be modification to suit the nutritional needs of infants. There is no requirement that the combination of DeWille in view of PURAC be proven in the prior art as "safe" as Applicants contend.

40. Applicant continues to argue (Remarks, pp. 5, 6, 7) that WHO fails to teach the use of L(+) lactic acid in formula and WHO teaches away from using L(+).

41. Applicant is directed to the "Evaluation" section of the WHO document, where it is noted that there is no limit of acceptable daily intake of lactic acid by man, other than the teaching against the use of D(-)-lactic acid and DL-lactic acid in infant foods. Lactic acid, to the examiner's knowledge, exists in only 3 forms, D(-)-lactic acid, L(+)-lactic acid, and the racemic mixture, DL-lactic acid. A teaching away from the use of D(-)-lactic acid and DL-lactic acid would have clearly indicated to one of ordinary skill that only the L(+)-lactic acid is suitable for use in infant foods. If, as applicant contends, the teachings of the WHO against DL- and D(-) lactic acids also constitute a teaching against L(+) lactic acid as it is a constituent of DL-lactic acid, Applicants are invited to provide evidence of other forms of lactic acid that might be added to infant foods.

42. The examiner also again directs applicant's attention to the Alm reference, which was cited in the conclusion of the Office Action mailed November 20, 2008, for further evidence in support of the use of L(+) lactic acid in infant nutritional formulas.

***Conclusion***

43. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nikki H. Dees/
Examiner, Art Unit 1794
/Lien T Tran/
Primary Examiner, Art Unit 1794

Nikki H. Dees
Examiner
Art Unit 1794

# EXHIBIT C

US006475539B1

(12) **United States Patent**
**DeWille et al.**

(10) **Patent No.: US 6,475,539 B1**
(45) **Date of Patent: *Nov. 5, 2002**

(54) **NUTRITIONALLY COMPLETE LOW PH ENTERAL FORMULA**

(75) Inventors: **Normanella T. DeWille**, Upper Arlington, OH (US); **Jeffrey G. Morris**, Brockville (CA); **Terrence B. Mazer**, Reynoldsburg, OH (US); **Paul S. Anloague**, Reynoldsburg, OH (US); **Amanda L. Smeller**, Loveland, OH (US); **Michael A. Chandler**, Westerville, OH (US); **Diane M. Garcia**, Westerville, OH (US); **Louis I. Ndife**, Columbus, OH (US)

(73) Assignee: **Abbott Laboratories**, Abbott Park, IL (US)

( * ) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/243,411**

(22) Filed: **Apr. 16, 1999**

**Related U.S. Application Data**

(63) Continuation-in-part of application No. 09/074,526, filed on May 7, 1998, now abandoned.

(51) **Int. Cl.**[7] ..... **A23H 4/12**; A23L 1/302; A23L 1/304; A23L 1/0524

(52) **U.S. Cl.** ..... **426/72**; 426/74; 426/573; 426/577; 426/580; 426/583

(58) **Field of Search** ..... 426/801, 573, 426/577, 72, 74, 11, 580

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | | |
|---|---|---|---|---|
| 3,692,532 | A | 9/1972 | Shenkenberg et al. | |
| 4,078,092 | A | 3/1978 | Nishiyama | |
| 4,212,893 | A | 7/1980 | Takahata | |
| 4,309,417 | A | 1/1982 | Staples | |
| 4,931,300 | A | 6/1990 | Monte | |
| 5,141,758 | A | 8/1992 | Monte | |
| 5,156,875 | A | 10/1992 | Monte | |
| 5,234,702 | A | 8/1993 | **Katz et al.** | |
| 5,389,391 | A | 2/1995 | Monte | 426/532 |
| 5,409,725 | A | 4/1995 | Connolly | 426/599 |
| 5,614,241 | A | 3/1997 | Monte | 426/532 |
| 5,641,531 | A | 6/1997 | Liebrecht et al. | |
| 5,690,975 | A * | 11/1997 | Akahoshi et al. | 426/577 |
| 5,700,513 | A * | 12/1997 | Mulchandani et al. | 426/573 |

FOREIGN PATENT DOCUMENTS

| | | |
|---|---|---|
| EP | 0 486 425 A2 | 10/1991 |
| EP | 0 765 609 | 9/1996 |
| EP | 0 639 335 | 6/1998 |
| GB | 1440161 | 1/1974 |
| WO | WO 96 29880 | 3/1996 |
| WO | WO 96 25054 | 8/1996 |
| WO | WO 96/29880 | 10/1996 |

OTHER PUBLICATIONS

Refreshing Dairy Beverages, Copenhagen Pectin A/S, A Division of Hercules Incorporated. copyright Copenhagen Pectin A/S 1998 Brochure.

Pederson, et al., "Influence of pectin on the stability of casein solutions studied in dependence of varying pH and salt concentration," Food Hydrocolloids, vol. 5, No. 4, pp. 323–328, 1991.

A.C. Spork, Acidifying Dairy–Based Drinks, Dairy Foods, Jul., 1994, pp. 34–36.

Ledward, D.A., "Protein–Polysaccharide Interactions," vol. 13, Polysaccharides in Food, School of Agriculture, University of Nottingham, pp. 205–217.

Thakur, B., et al., Critical Reviews in Food Science and Nutrition, 37(1):47–73, 1997.

McCue, N., *R & D Applications, Juice With Milk Has Family Appeal*, Prepared Foods, Sep. 1994, p. 87.

Pediasure®, Complete Liquid Nutrition for children 1–10 years, Ross Medical Nutritional Products Handbook, 1998.

Ensure®, Complete, Balanced Nutrition®, Ross Medical Nutritional Products Handbook, 1998.

* cited by examiner

*Primary Examiner*—Helen Pratt
(74) *Attorney, Agent, or Firm*—Nickki L. Parlet; J Michael Dixon

(57) **ABSTRACT**

This invention is directed to a low pH nutritional formula that contains high levels of macronutrients, vitamins and minerals. The pH of the enteral formula is from about 3.0–4.6 and delivers at least 25% of the RDI for selected vitamins and minerals in a 237 ml. serving. The enteral formula uses a stabilizing system comprising high methoxy pectin to stabilize the protein and a unique process to produce the formula.

**9 Claims, No Drawings**

# NUTRITIONALLY COMPLETE LOW PH ENTERAL FORMULA

## CROSS REFERENCE

This application is a continuation-in-part of U.S. patent application Ser. No. 09/074,526 which was filed on May 7, 1998, now abandoned.

## TECHNICAL FIELD

This invention relates to a low pH enteral formula that contains high levels of macronutrients, vitamins and minerals. The inventive formula possesses excellent physical stability and taste. The inventive formula also exhibits a shelf life of at least one year in a liquid state with minimal or no sedimentation. The formula of this invention utilizes a unique stabilizing system, antioxidant system and method of production to produce a physically stable, low pH nutritional beverage that contains high levels of protein and delivers at least 25% of the Reference Daily Intake (RDI) for selected vitamins and minerals in approximately a 250 ml serving. The formula can be adjusted to meet the nutritional needs of adults and children over 4 years age or to children under 4 years of age.

## BACKGROUND OF THE INVENTION

Nutritionally complete, balanced, isotonic enteral formula have been known for some time. These formula are designed to be used as the sole source of nutrition for a patient or as a supplement. Typically, these liquid products are designed to provide approximately 100% of the patient's nutritional needs in about 1,000 ml. These formula may also be designed to be disease specific in that they fulfill the special nutritional requirements of patients afflicted with conditions such as glucose intolerance, pulmonary disease or those who have been subjected to surgery or trauma. These nutritionally complete formula are known by the artisan to be prone to physical stability problems such as syneresis and the formation of non-dispersible sediments. These problems are caused by the high level of protein, fats and minerals that these nutritional formula must contain to provide adequate nutrition in a reasonable volume.

Most nutritionally complete enteral formula have a neutral pH and have flavors that are limited to the traditional "milkshake" types. Acidified or low pH nutritionals offer several advantages in that the possibility of microbial contamination can be reduced and a variety of refreshing fruit flavors can be used. However, acidification of the traditional enteral formula leads to protein precipitation, phase separation and the formation of non-dispersible sediments. These problems result in the product being aesthetically unacceptable to the patient and the formula may fail to deliver adequate nutrition due to the formation of the non-dispersible sediments.

PediaSure®, complete liquid nutrition, is manufactured by the Ross Products Division of Abbott laboratories (Columbus, Ohio) and is designed to be a nutritionally complete, balanced, isotonic enteral formula especially designed for tube or oral feeding of children 1 to 10 years of age. This product is used as a sole source of nutrition or as a supplement and meets or exceeds 100% of the U.S. RDI's for protein, vitamins and minerals for children 1–6 years of age in 1000 mL and for children 7–10 years of age in 1300 mL. PediaSure contains 1.0 calorie per ml and has a caloric distribution of 12.0% protein, 44.8% fat and 43.9% carbohydrate. This product has a pH of about 7.0 and is available in a variety of "milk shake" flavors. This product is not intended for infants under 1 year of age.

Ensures®, complete, balanced nutrition, is manufactured and distributed by the Ross Products Division of Abbott



Laboratories for adult consumption. This formula contains 1.06 calories per mL and has a caloric distribution of 14% from protein, 31.5% from fat and 54.5% from carbohydrate. The formula meets or surpasses 100% of the U.S. RDI for vitamins and minerals for adults and children 4 or more years of age in 2000 calories (two quarts or 1.892 L). Ensure is available in numerous milk shake type flavors. It is also available in high nitrogen, high calorie as well as with dietary fiber. While PediaSure® and Ensure® nutritional products have been accepted by the public and health care providers, a need exists to present the patient with flavor alternatives that will increase patient enjoyment and thereby compliance.

Numerous investigators have reported on various approaches to overcome the problems associated with low pH formula. U.S. Pat. No. 5,409,725 to Connolly discloses a process for stabilizing protein in an acidic media through a chemical reaction between the protein and galactomannan to produce a glycoprotein. The galactomannan used by Connolly is a linear polysaccharide, such as locust bean gum (LBG) and guar gum. This patent also discloses the optional use of a heat stability agent such as pectin or high methoxy pectin. This reference provides one example of a low pH (2.0–6.0), milk based beverage that was not fortified with the levels of calcium and protein required for a nutritionally complete beverage. As will be demonstrated in the comparative examples herein, the stabilization system of U.S. Pat. No. 5,409,725 is not effective in a low pH nutritional matrix that contains high levels of protein and macronutrients.

U.S. Pat. No. 3,692,532 to Shenkenberg, et al., discloses a stable milk-fruit juice beverage consisting essentially of milk, fruit juice, sweetener and sodium carboxymethylcellulose (NaCMC) wherein the beverage has a viscosity of less than 30 cp and is stable at pH levels below 5.0. This patent teaches that sufficient time be allowed for the carboxyl groups of the carboxymethylcellulose (CMC) to react with the cascin molecules to form a complex which results in a stable, free flowing, non-congealing, low-viscosity beverage.

U.K. Patent 1,440,161 to Nishiyama teaches a milk-fruit juice beverage which contains 4.2–6.2 w/v % of NaCMC as a stabilizer to prevent the coagulation of milk protein, 10–50 w/v % of a fruit juice and 3.1–5.0 w/v % of citric, lactic, malic or tartaric acid. In the process of Nishiyama, the NaCMC is added to hot water with vigorous agitation at neutral pH and then the juice is added. After cooling, the solution is acidified with the recited food grade acid. No additional protein, fat, carbohydrates, minerals and/or vitamins are added to the beverage. In a related case, U.S. Pat. No. 4,078,092, Nishiyama discloses a milk-apple juice drink having a pH of 3.6–4.5 wherein 100 ml of the drink contains 4.2–6.0 gms of a carboxylic acid.

Pedersen, et al., in an article entitled: "Influence of pectin on the stability of casein solutions studied in dependence of varying pH and salt concentration", *Food Hydrocolloids*, Vol. 5, No. 4, pp. 323–328, (1991), discusses pectin-casein interactions and teaches that the addition of pectin to casein solutions lowers the pH value at which the casein precipitates. The effect was studied in the presence of various salts and polysaccharides and concluded that the stabilization of pectin-casein systems is primarily of an electrostatic nature.

U.S. Pat. No. 4,212,893 to Takahata discloses a stable, emulsified, acidified whole milk beverage made by: (1) preparing an aqueous solution of LBG and adding it to whole milk at a concentration to result in 0.3% by weight LBG based on the total weight of the beverage; (2) acidifying the milk emulsion with fruit juice or organic acids to a pH of between 3.4 and 3.6; (3) stabilizing the emulsion by stirring the acidified mixture for 10–30 minutes; (4) homog-

onizing the acidified emulsion; and (5) sterilizing and packaging the acidified emulsion.

EP 0 486 425 A2 to Kvamme relates to a nutritional formulation containing from 40–90% of the calories from carbohydrates, from 2–30% of the calories from protein, from 0–35% of the calories from fat and from 0–17% of the calories from fiber. The protein source is at least 60% by weight whey protein concentrate and the pH of the formulation is 3.5–3.9. This reference discloses the use of polyglycerol esters and hydrolyzed guar gum as an emulsification system for the nutritional product containing fat and fiber.

U.S. Pat. Nos. 4,931,300; 5,156,875; 5,141,758; and 5,389,391 to Monte disclose various low pH, antimicrobial food compositions. These foods are powdered compositions that may later be reconstituted with liquids. The Monte compositions usually comprise a protein component, a fat component and a carbohydrate component. Monte also teaches the use of emulsifiers and antimicrobial agents such as sorbate and benzoate's. The U.S. Pat. No. 5,156,875 specifically discloses the use of a binary stabilizer system which comprises a modified starch such as modified potato starch and a cellulose gum. In one example, Monte replaces his stabilizing system with pectin. He reports that in less than six (6) hours, particulate began settling and separating out of the pectin stabilized solution to form a layer of material at the bottom of the beaker. Monte suggests that pectin is inappropriate for low pH food compositions. In U.S. Pat. No. 5,389,391, Monte teaches and discloses a low pH protein stabilizer system comprising a pectin substance and methyl cellulose. Monte teaches that this low pH protein stabilizer system is from 0.1–20% by dry weight pectin, or another pectin substance, in combination with 0.001–10.0% by dry weight of NaCMC or another methyl cellulose. The Monte patents fail to suggest a method of producing a low pH beverage that contains at least 100% of the daily nutritional needs of an adult for calcium, vitamin D, vitamin C, vitamin K and vitamin E in approximately 1000 ml (a single serving of approximately 250 ml provides 25%). Monte also specifies that once the product is reconstituted, it has a shelf life of several days.

U.S. Pat. No. 5,614,241 to Monte discloses a nutritionally balanced, water soluble, powdered food composition which, when mixed with water, has a low pH and high antimicrobial activity. This patent discloses the use of 1–5% by weight of a pectin substance for preventing the precipitation of protein. This patent also teaches the use of a buffer system for the low pH drink which comprises sodium citrate and citric acid. The preferred pH of this beverage is less than about 4.75 and under the most preferred conditions is less than about 4.5. This patent does not address the special problems and parameters of a low pH enteral formula that contain high levels of macronutrients, vitamins and minerals. Further, it is known that nutritional powders experience phase separation problems upon reconstitution. The patent specifies that the reconstituted product has a shelf life of several days.

PCT/US96/02245 (WO 96/29880) to Yang, et al., discloses a product which contains from 5 to about 99.8% milk, from about 0.05 to about 0.8% of a food stabilizer and a food acid. This application specifically teaches the acidification of the mixture while the particle size of the protein/stabilizer particles is less than about 0.8 microns. This reference teaches that various food stabilizers can be employed, such as gum arabic, gelatin, xanthan, locust bean and pectin. A blend of pectin and CMC is specifically disclosed in this reference. This reference does not address the special needs of nutritional products having high levels of protein and nutrients such as calcium.

U.S. Pat. No. 5,641,531 to Liebrecht, et al., relates to a substantially clear liquid nutritional supplemental that comprises 1–10% by weight whey protein isolate, at least one source of carbohydrate having a DE of at least 10, vitamins, trace minerals and ultra trace minerals. The pH of the Liebrecht, et al., beverage is from 2.8 to about 3.3, has a caloric density of at least 1.0 kcal/ml and uses no stabilizing system. This patent is not concerned with nutritionally complete beverages as it discloses a beverage that is essentially devoid of added macronutrients and fat.

U.S. Pat. No. 5,234,702 to Katz, et al., relates to an antioxidant system for powdered nutritional products. The powdered nutritional products contain an unsaturated lipid component which is stabilized by a mixture of ascorbyl palmitate, β-carotene and citrate. This patent does not suggest the use of the antioxidant system for use in a low pH beverage that contains high levels of protein and macronutrients.

Hercules Food Ingredients, Wilmington, Del., supplies a pectin-type ingredient that is taught to stabilize a juice/milk mixture. GENU® (registered trademark of A/S Pektinfabrik of Copenhagen, Denmark) pectin-type JM is known to control stability and control viscosity of sour milk drinks. A description of the use of GENU® pectin in a beverage can be found in McCue, N. (Sr. ed.) Prepared Foods, September 1994, page 87. The use of high methoxyl pectin in dairy/juice products is disclosed by A. C. Speck in "Acidifying Dairy-Based Drinks", *Dairy Foods*, July, 1994, pages 34–36. Neither of these references address the problems associated with a low pH beverage that contains high levels of protein and macronutrients.

The ability of acidic polysaccharides such as CMC to inhibit protein precipitation at the isoelectric point of the proteins has been used in the preparation of fruit-flavored milk drinks. CMC has been found particularly effective in keeping milk proteins in solution. For a review of protein-polysaccharide interactions, see D. A. Ledward, "Protein-Polysaccharide Interactions", Vol. 13, *Polysaccharides in Food*, School of Agriculture, University of Nottingham, pages 205–217.

Thakus, et al., in *Critical Reviews in Food Science and Nutrition*, 37(1):47–73 (1997) provide a review of the chemistry and uses of pectin. This publication does not address the special problems associated with low pH and viscosity milk/juice beverage that provides complete nutrition to a human in about 1 liter.

Numerous investigators have attempted to overcome the problems associated with low pH milk protein-containing beverages. Various processing techniques and stabilizing systems have been proposed to reduce or eliminate phase separation, sedimentation and high viscosities, all with limited success. None of the prior art investigators have overcome these problems to produce an acceptable low viscosity, low pH, high protein, high mineral, fat-containing beverage. None of these investigators have developed a low pH, high protein, high mineral, fat containing beverage having a shelf life of at least one year. The present invention, which is illustrated in the following Examples, provides a method and combination of components to overcome the shortcomings of the prior art.

## SUMMARY OF THE INVENTION

In general, this invention relates to a low pH nutritional beverage of low viscosity that contains high levels of protein, vitamins and minerals having an extended shelf life and excellent physical stability. The invention also relates to a method of preparing said low pH nutritional product which is accomplished through the use of a unique mixture of starting materials and a series of specific steps. In one embodiment of the invention, these beverages are low pH products suitable for use as a complete nutritional product for children of 1–4 years of age, or for adults and older

children. A complete nutritional product can be used as a sole source of nutrition for the patient, thus special attention must be paid to the protein, carbohydrate, lipid, mineral and vitamin levels. Patients can receive 100% of their nutritional requirements from such sole nutritionals.

Alternatively, these same low pH beverages can be formulated to serve as nutritional supplements. Supplements are not intended to serve as sole source nutritionals and do not supply 100% of a patients nutritional needs. They will be fortified to provide high levels of one or more nutrients. For example, low fat, high calcium products are desirable in adult females. Likewise high protein, low fat beverages that have been fortified with vitamins and calciums are advantageous in children. Other such applications will be readily apparent to one skilled in the art.

As those skilled in the art of nutrition are aware, many countries around the world have set standards or reference values for the intake of vitamins, minerals, protein, fat and carbohydrates for the typical human being. For example, the European community has set Population Reference Intakes (PRI) and Canada has recommended Daily Intakes. These countries often have separate standards for adults (i.e., over two (2) years of age) and children (i.e., under two (2) years of age).

As used herein and in the claims, the term "RDI" means the standard set for the specified nutrient in the country in which the low pH beverage is to be sold. The RDI may be specific for certain age groups (i.e., children under two (2) years of age). For example, if the inventive low pH nutritional is intended to be suitable for sole source nutrition and is to be sold in Germany, 100% of the Recommended Daily Intake in Germany for protein, calcium, vitamin C, folic acid, vitamin D, vitamin E and vitamin K will be supplied in approximately 1000 ml of the nutritional product. If intended as a supplement, then the beverage will be fortified with the relevant nutrients according to German standards. The RDI's vary slightly from country to country, if at all, and it is well within the purview of the artisan to obtain the recited value and adjust the beverage of this invention accordingly. Unless stated otherwise, all percentages recited herein and in the claims are percents by weight of the recited component to the weight of the final product.

Therefore, it is a principal object of the invention to provide an improved enteral nutritional composition for adults and children. Another object of the invention is to provide a low pH liquid food composition which: (i) utilizes a protein system selected from sodium case mate, calcium caseinate, whey protein, milk protein concentrate, milk protein isolate (a.k.a., total milk protein), whey protein concentrate and mixtures thereof, and (ii) a novel stabilizing system which generally prevents protein and calcium from precipitating or separating from the liquid food composition.

One aspect of the beverage of this invention is that a greater variety of flavors can be produced when compared to the conventional beverage having a pH of about 7.0. The beverage of the invention is designed to provide superior nutrition in a low viscosity product that possesses superior physical stability properties. As a general guideline, the beverage typically contains from about 3–20 gms of protein, from about 0–20 gms of fat, from about 100–450 calories and at least 25% of the RDI of certain vitamins and minerals, in approximately 250 ml. More typically, the beverage contains from about 3–15 gms of protein, from about 0.5–13.0 gms of fat, from about 140–300 calories and at least 25% of the RDI of certain vitamins and minerals in approximately 250 ml. The pH range of the beverage can range from about 3.0–4.6, with about 4.0–4.35 being preferred.

In yet a more preferred embodiment, the beverage contains about 5–11 gms of protein, about 1–12 gms of fat, about 190–250 calories and at least 25% of the RDI for calcium, vitamins C, D, K and E and selenium in a single serving, having an approximate volume of 250 ml, and wherein the beverage has a viscosity of less than 150 cps when measured with a Brookfield viscometer with a #1 spindle at 20° C., more preferably less than 75 cps and most preferably less than 35 cps.

The low pH matrix of the beverage provides a platform for a product with flavor diversity, no vitamin or mineral aftertaste, much lower risk of microbial spoilage, and much lower heat treatments of product which improves vitamin stability's and flavor.

There is further disclosed a liquid nutritional product having a pH of from about 3.0–4.6 comprising:

(a) from about 45–95% by weight water;

(b) from about 1.0–15%, and more typically about 3–15%, by weight of a source of amino nitrogen selected from sodium caseinate, calcium caseinate, whey protein, milk protein isolate, milk protein concentrate and mixtures thereof;

(c) from about 0.1–3.3% by weight of a stabilizer system comprising high methoxy pectin;

(d) from about 1–30%, and more typically about 1–20%, by weight of a carbohydrate;

(e) from about 0–10%, and more typically about 0.5–10%, by weight of an edible oil;

(f) vitamins and minerals, wherein said beverage contains at least 100% of the RDI for protein, calcium, vitamin C, folic acid, vitamin D, vitamin E and vitamin K in approximately 1000 ml;

(g) optionally, from about 0.05–1.0% by weight of a calcium source selected from the group comprising calcium glycerophosphate, calcium citrate, calcium lactate, calcium gluconate, calcium phosphate tribasic and mixtures thereof;

(h) optionally from about 0.1–10% by weight of an acid system comprising of at least one food grade acid selected from the group comprising citric acid, phosphoric acid, tartaric acid, lactic acid, malic acid, gluconodelta lactone, dilute hydrochloric acid, acetic acid, and mixtures thereof; and;

(i) optionally from about 0.01–5% by weight of an emulsifier system comprising at least one component selected from the group comprising lecithin, monoglycerides, diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, and mixtures thereof.

There is also disclosed a liquid nutritional product having a pH of about 4.0 to about 4.4 comprising:

(a) from about 60–90%, and more typically about 70–90%, by weight water;

(b) from about 1–8%, and more typically about 1–6%, by weight of a source of amino nitrogen, wherein the source of amino nitrogen is a mixture of milk protein isolate and calcium caseinate;

(c) from about 0.8–2.0% by weight of a stabilizer system comprising high methoxy pectin;

(d) optionally from about 0.1–1.0% by weight of a calcium source, wherein the calcium source comprises a mixture of calcium glycerophosphate and calcium citrate;

(e) optionally from about 0.3–2.0% by weight of a food grade acid, and more preferably the food grade acid is a mixture of citric acid and phosphoric acid;

(f) optionally from about 0.1–5.0% by weight soy lecithin;

(g) optionally from about 0.1–3% by weight of an anti-oxidant system, comprising ascorbyl palmitate, mixed tocopherols and citrate;

(h) from about 5–30%, and more typically about 10–25%, by weight of a carbohydrate;

(i) from about 0–10%, and more typically about 0.5–5%, by weight of an edible oil; and

(j) vitamins and minerals wherein the nutritional product contains at least 25% of the RDI for protein, calcium, vitamin C, folic acid, vitamin D, vitamin E and vitamin K in a single serving of approximately 250 ml.

A further embodiment of the invention relates to a nutritionally complete composition for children of 1 to 4 years of age having a pH of about 4.0 to about 4.4 comprising:

(a) from about 70–90% by weight water;

(b) from about 2–4% by weight of a source of amino nitrogen;

(c) from about 0.5–1.5% by weight of high methoxy pectin;

(d) vitamins and minerals, wherein the nutritional composition contains at least 25% of the RDI for children 1 to 4 years of age for protein, calcium, vitamin C, thiamine, iron, vitamin $B_6$, folic acid, vitamin $B_{12}$, zinc, vitamin D, vitamin E and vitamin K in approximately 250 ml.

(e) from about 0–6.0% by weight of an edible oil, wherein the edible oil comprises a high oleic oil;

(f) from about 5–15% by weight of a carbohydrate, wherein the carbohydrate comprises hydrolyzed corn starch with a DE of from 10 to 25;

(g) optionally, from about 0.1–3% by weight of an anti-oxidant system comprising ascorbyl palmitate, mixed tocopherols and citrate;

(h) optionally, from about 0.1–0.5% by weight of an emulsifier system comprising soy lecithin, monoglycerides and diglycerides;

(i) optionally, from about 0.5–1.0% by weight of a mixture of citric acid and phosphoric acid; and;

(j) optionally from about 0.0 to 0.5% by weight of calcium phosphate tribasic.

The source of amino nitrogen in the pediatric beverage preferably comprises milk protein isolate.

A representative RDI is the U.S. RDI which refers to the United States Food and Drug Administration (FDA) regulations establishing a Reference Daily Intake (RDI's) for various nutrients such as protein, vitamins and minerals for adults and children over four years of age and for children under four years of age and older than 13 months.

Table 1 sets forth the U.S. RDI's for selected nutrients as of the date of filing this application.

TABLE 1

| | U.S. RDI's | |
|---|---|---|
| NUTRIENT | Adults and Children over 4 years | Children under 4 years |
| Protein | 65 g* | 20 g* |
| Vitamin A | 5,000 IU | 2,500 IU |
| Vitamin C | 60 mg | 40 mg |
| Thiamin | 1.5 mg | 0.7 mg |
| Riboflavin | 1.7 mg | 0.8 mg |
| Niacin | 20 mg | 9.0 mg |
| Calcium | 1.0 g | 0.8 g |
| Iron | 18 mg | 10 mg |
| Vitamin D | 400 IU | 400 IU |
| Vitamin B6 | 2.0 mg | 0.7 mg |
| Folate | 0.4 mg | 0.2 mg |
| Vitamin B12 | 6 mcg | 3 mcg |
| Phosphorus | 1.0 g | 0.8 g |
| Iodine | 150 mcg | 70 mcg |
| Magnesium | 400 mg | 200 mg |
| Zinc | 15 mg | 8 mg |
| Copper | 2 mg | 1 mg |
| Biotin | 0.3 mg | 0.15 mg |
| Pantothenic acid | 10 mg | 5 mg |
| Vitamin K | 80 mcg | 15 mcg |
| Selenium | 70 mcg | 20 mcg |
| Manganese | 2 mg | n/a |
| Chromium | 120 mcg | n/a |
| Molybdenum | 75 mcg | n/a |
| Chloride | 3,400 mg | n/a |

*If protein efficiency ratio of a protein is equal to or better than that of casein U.S. RDI is 45 gms for adults and 16 gms for children under 4 years of age.

n/a = not applicable

Table 2 sets forth some representative RDI's that have been established in the European Community (EP), Canada and Germany.

TABLE 2

| | RDI's of Canada, EP and Germany Per Day | | | | |
|---|---|---|---|---|---|
| | CANADA | | | | |
| NUTRIENT | Persons 2 years of age and older INTAKE | Infants or children less than 2 years of age INTAKE | GERMANY MINIMUM | GERMANY MAXIMUM | EP Average Requirement * Adult |
| Calcium (mg) | 1100 | 500 | 800 | 1800 | 550 |
| Vitamin C (mg) | 60 | 20 | 40 | 120 | 30 |
| Folate (mcg) | 220 | 65 | 300 | 400 | 140 |
| Vitamin D (mcg) | 5 | 10 | 2.5 | 15 | 0–10 |

TABLE 2-continued

RDI's of Canada, EP and Germany Per Day

| | CANADA | | | | |
|---|---|---|---|---|---|
| | Persons 2 years of age and older | Infants or children less than 2 years of age | GERMANY | | EP Average Requirement |
| NUTRIENT | INTAKE | INTAKE | MINIMUM | MAXIMUM | * Adolt |
| Vitamin E (mg) | 10 | 3 | 6 | 24 | — |
| Vitamin k (mcg) | — | — | 30 | 120 | — |

* Taken from Reports of the Scientific Committee for Food, (31st series) "Nutrient and energy intakes for the European Community."

There is also disclosed a method for preparing a nutritional composition, said method including the steps of: (a) preparing an oil blend wherein said oil blend comprises an edible oil, an emulsifier, vitamins A, D, E and K, ascorbyl palmitate and mixed tocopherols; (b) preparing a carbohydrate/mineral slurry by mixing pectin with water at less than 10% by weight total solids under high shear and at a temperature between 65 and 71° C. (150–170° F) for at least ten (10) minutes and thereafter adding a source of major minerals, trace/ultra trace minerals and carbohydrates; (c) preparing a protein slurry by combining protein with water, under agitation, to obtain an aqueous mixture of at least 8% by weight solids; (d) combining the protein slurry, carbohydrate/mineral slurry and the oil blend to form a protein/carbohydrate/ mineral/oil mixture; (e) homogenizing the protein/carbohydrate/ mineral/oil mixture through a homogenizer at a pressure of at least 17 MPa (2,500 Psig) to form a homogenized blend; (f) acidifying the homogenized blend of step (e) with an edible acid to a pH ranging from about 3.0–4.6; (g) adding to the homogenized mixture at least one component selected from the group consisting of flavors, colors, vitamins, fruit juices, water, folic acid, cysteine and ascorbic acid; (h) homogenizing the acidified mixture from step (g) by passing the mixture through a homogenizer at a pressure of at least 17 MPa to form an aqueous food solution; and (i) heating said aqueous food solution to a sterilization temperature for a time sufficient to kill or inactivate substantially all microorganisms in said food solution.

One aspect of the present invention relates to the above described unique process of manufacture which produces a beverage with excellent physical stability even after retort sterilization, aseptic packaging and hot-fill processes. It has been discovered that preparing the carbohydrate/mineral slurry by initially mixing pectin with water at less than about 10% by weight total solids prior to the addition of the calcium, trace/ultra trace minerals and carbohydrates is important to producing a physically stable product. An additional method of preparing the inventive beverage, especially a pediatric beverage, comprises the steps of combining the source of amino nitrogen (i.e., milk protein isolate) with the pectin and then subjecting the-mixture to homogenization at a pressure of at least 6.8. MPa, more preferably, 17.6 MPa (2,000 psig). The homogenized blend is then combined with the other ingredients to produce the beverage. This step of homogenizing the protein and pectin is in addition to the two homogenizations described below.

Further, it has been discovered that two homogenization steps are required, one prior to and one subsequent to acidification, to provide a beverage of acceptable physical stability over shelf life. The first homogenization should be at a pressure of at least 17 MPa (2,500 psig) and more preferably is a two stage homogenization at about 27 MPa (4000 psig) and about 3.5 MPa (500 psig). After acidification, the homogenization pressure of a single stage homogenizer should be at least 17 MPa (2,500 psig) and preferably at least 20.4 MPa (3,000 psig). If this last homogenization is after acidification, but prior to a final heat treatment, an additional homogenization of at least 6.8 MPa (1,000 psig) should be conducted prior to filling. More preferably, this additional homogenization should be at least 10.3 MPa (1,500 psig).

It will be understood by those skilled in the art that the described nutritional formula can be in a ready-to-feed form or in the form of a concentrate or powder. Preparation of the concentrate and powder forms can be accomplished using known techniques and equipment.

In one embodiment of the invention, the nutritional formula of the invention has a pH of from about 3.0–4.6 and comprises:

(a) a source of amino nitrogen comprising milk protein isolate and calcium caseinate;

(b) a stabilizer system comprising high methoxy pectins, optionally in combination with microcrystalline cellulose and sodium carboxymethylcellulose;

(c) a source of calcium comprising calcium citrate and calcium glycerophosphate;

(d) an antioxidant system comprising mixed tocopherols and ascorbyl palmitate; and

(e) L-cysteine.

The nutritional formula may additionally comprise:

(a) an antimicrobial system comprising potassium sorbate, potassium benzoate and mixtures thereof;

(b) a source of edible oil selected from high oleic safflower oil, soy oil, fractionated coconut oil, high oleic sunflower oil, corn oil, canola oil and mixtures thereof; and

(c) sources of vitamin C, folic acid, vitamin D, vitamin E and Vitamin K at concentrations to achieve at least 25% of the U.S. RDI in approximately 250 ml.

It should be understood that the levels of the vitamins can be adjusted to meet the needs of humans four (4) years of age and older and for children of thirteen (13) months to four (4) years of age.

A further embodiment of this invention is a process for improving the long term physical stability of low pH beverages containing substantial quantities of protein, calcium, vitamins and other minerals. A characteristic problem of low pH beverages is the tendency of sediment to form at the bottom of the beverage container. This sediment contains calcium, other minerals, protein, etc. Asides from the unattractiveness of this sediment, these precipitated nutrients cannot be shaken back into solution and do not provide the nutrients required to maintain the health of the patient.

A new stabilizer has been discovered that will solve this problem. High methoxy pectin, in sufficient quantities, will produce a low pH beverage that will remain physically stable for at least one year. Physical stability refers to either an absence of sediment or a significant reduction in the occurrence of the formation of sediment, for at least a 12-month period. Alternatively, a combination of stabilizers may be utilized to produce this same effect.

A new source of calcium has also been discovered for low pH beverages containing substantial quantities of protein. It has been discovered that an admixture of calcium glycerophosphate and calcium citrate can be utilized in such beverages without having adverse effects upon the viscosity and stability of the beverages. Certain calcium sources, such as calcium citrate malate, caused the protein to gel in a relatively short period of time and thus rendered the beverages undrinkable. Such finding were unexpected since calcium citrate malate is routinely added to acidic beverages such as orange juice.

## DETAILED DESCRIPTION OF THE INVENTION

Acidified milk-based drinks have gained popularity throughout the world over the last five (5) to ten (10) years. Milk can be acidified microbiologically, but also can be blended with fruit juices and edible acids to produce beverages that possess a refreshing natural fruit taste due to their low pH. However, the low pH causes a number of problems that are aggravated when a beverage contains high concentrations of protein and certain nutrients such as calcium. The beverage and method of the present invention, including the materials used therein, the particular process steps and the characteristics of the nutritional beverage prepared according to this invention, are described in detail as follows:

### A. Protein System

For purposes of the present specification, the term "caseinate" means the product resulting from the sodium or calcium hydroxide neutralization of acid casein. Acid casein is used in its broadest sense and covers both traditional acid casein, obtained directly by acidifying milk, and acid casein obtained indirectly, such as, for example, a re-acidified rennet casein. For purposes of the present specification, the terms "whey protein concentrate" and "whey protein isolate" are defined to mean a water soluble or suspendible, essentially undenatured protein fraction derived from cheese whey or as a by-product of casein production. Whey protein is a naturally occurring protein and is specific and identifiable in terms of its composition and is not necessarily dependent upon the process used to produce it. Whey protein may be obtained by methods such as ultrafiltration or gel filtration. Milk protein isolate (a.k.a., total milk protein) can also be used in the beverage and is available from the Kerry Ingredients of Beloit, Wis. and total milk protein from New Zealand Milk Products of Santa Rosa, Calif. In one embodiment of the invention, a 65/35 weight % mixture of the milk protein isolate and calcium case mate is preferably used in the adult product. In other embodiments, the beverage uses milk protein isolate at 60 weight % of total protein or total milk protein at 100%. Milk protein isolate is 82% casein and 18% whey and is manufactured by ultrafiltration, thereby the whey to casein ratio is the same as regular milk. This protein is highly desirable in the inventive beverage as it possesses superior flavor and functionality.

For certain low pH beverages in which the caloric density is increased beyond 1.0 kilocalorie per ml, it may be desirable to utilize partially hydrolysed whey as part of the protein source. Soy protein isolate may also be used. The amount that can be incorporated can vary widely, but will typically range from 10 to about 30 w/w % of the total protein present in the system. This partially hydrolysed whey will serve to help control the osmolality of the final formula. Partially hydrolysed whey is available from numerous commercial sources including Kerry Ingredients of Beloit, Wis. Gelatin, which is obtained from fish, pigs, or cows, may also be used to control osmolality. The amount of gelatin will fit within the ranges described above and is available from numerous commercial sources.

The amount of protein used in the present beverage may vary widely, but for most applications from 1–15% by weight is suitable, more typically between about 1–8 % by weight and more often between about 1 and 6% by weight. In general, the source of amino nitrogen can include any known source such as soy protein, vegetable proteins, cereal proteins, meat, fish and the like. In the nutritionally complete child product, it has been determined that milk protein isolate is the preferred source of amino nitrogen, especially when the product is terminally sterilized. The amino acid profile of the protein system is preferably designed to meet the human amino acid requirement for adults. See *Recommended Daily Allowances*, 10th Edition, FNB/NRC.

### B. Stabilizer System

Various food stabilizers can be employed in the present invention and include hydrophilic colloidal stabilizers known as gum arabic, pectins, gelatin, xanthan and LBG as well as the anionic polymers derived from cellulose such as CMC. These stabilizers are water soluble and tolerate a low pH which is encountered in the inventive beverage.

Pectins are used in the present invention to enhance physical stability and control the viscosity of the beverages. The pectin stabilizes the milk proteins to yield products without significant sedimentation and phase separation (i.e., physical stability) and ensures a smooth mouthfeel without any "sandiness" and they help control viscosity by stabilizing free water. Pectins are a class of complex polysaccharides found in the cell walls of higher plants. The number of plant sources that are used for the commercial production of pectins is fairly limited. At present, apple pomace and citrus peels are the main sources of commercially acceptable pectins. They, however, produce slightly different pectins, which make one or the other more suitable for specific applications. Other sources of pectin include sugar beets and the seed heads of sunflowers. Citrus pectins are preferred in the present invention and most preferred is orange pectins.

The ability of pectins to form a gel depends on the molecular size of the molecule and the degree of methoxylation (DM). The chemical structure of pectin has been the subject of many scientific investigations. Elucidation of pectin structure is important to understanding its role in food processing and as a nutritional fiber. Like most other polysaccharides, pectins are both polymolecular and polydisperse; that is, they are heterogeneous with respect to both chemical structure and molecular weight.

The composition of pectin varies with the source and conditions of extraction, location, and other environmental factors. Based on solubility, two different types of pectins exist: water-soluble or "free pectin" and the water-insoluble pectins. Solubility in water is related to the degree of polymerization and the number and distribution of methoxyl groups.

The most unique property of pectins is their ability to form gels in the presence of $Ca^{2+}$ ions or sugars and acid. Depending on the DM, pectins are classified into: 1) low methoxy (LM) pectin with a DM of 25–50% and 2) high methoxy (HM) pectin of 50–80% DM. LM and HM pectins form gels in the presence of calcium ions and acid, respectively. The mechanism of gel formation is different in both

HM and LM pectins. HM pectins form gels if the pH is below 3.6 and a cosolute is present.

Pectins have always been a natural constituent of human foods and its use is allowed in all the countries of the world. Pectin has been used in a number of foods such as jellies, preserves, jams, dietetic soft drinks, ice cream and as a fat or sugar replacement in low-calorie foods. Pectins also have uses in the pharmaceutical industry.

The pectins useful in the present invention are the HM pectins and are available from The Copenhagen Pectin Factory Ltd. of Denmark and Hercules Food Ingredients, Wilmington, Del. The preferred HM pectins are known as GENU® JMJ, GENU® JM, GENU® JM 150, and GENU® YM100H manufactured by Hercules Food Ingredients. The GENU® HM pectins are used in this invention to stabilize the protein at low pH.

The concentration of the HM pectin used herein can range from about 0.1–3.3% by weight, more preferably 0.1–2% by weight, even more preferably from about 0.5–1.5% by weight and most preferably from about 0.6–1.25% by weight. The amount of HM pectin, such as GENU, used, is dependent, in part, on the level of protein present in the beverage product. In general, the greater level of protein, the more HM pectin will be required to stabilize the low pH beverage. The stabilizing system can comprise the use of high methoxy pectin alone, or alternatively the high methoxy pectin may be used in combination with other stabilizers. For example, the stabilizing system may contain materials such as specially processed pectins which reduce sediment and phase separation through increasing viscosity (i.e. Slendid 200) and micro crystalline cellulose. Slendid 200 is a high ester pectin which is extracted from citrus peel and standardized by the addition of sucrose, however, the molecular structure has been modified during the extraction process to build viscosity and hold water.

One source of microcrystalline cellulose useful in the invention is Avicel® cellulose gel from the FMC Corporation of Philadelphia, Pa. One preferred form of Avicel is Avicel CL-611 which is a colloidal grade and comprises a 85% by weight microcrystalline cellulose (MCC) and 15% by weight sodium carboxymethylcellulose (CMC). One aspect of the present invention resides in the discovery that the low pH beverage can be adequately stabilized against physical degradation over shelf-life through the use of high methoxy pectins (HM Pectins) alone, or optionally in combination with MCC and CMC. The amount of HM pectins, CMC and MCC used in the inventive formula, as a % by weight of the formula, can vary as follows:

| | | |
|---|---|---|
| HM Pectin | about | 0.1–2.0 w/w % |
| CMC | about | 0.005–0.5 w/w % |
| MCC | about | 0.005–1.0 w/w % |

In a more preferred embodiment, the ranges are as follows:

| | | |
|---|---|---|
| HM Pectin | about | 0.5–1.0 w/w % |
| CMC | about | 0.01–0.3 w/w % |
| MCC | about | 0.05–0.1 w/w % |

In yet a more preferred embodiment, the ranges are as follows:

| | | |
|---|---|---|
| HM Pectin | about | 0.7–0.9 w/w % |
| CMC | about | 0.01–0.02 w/w % |
| MCC | about | 0.07–0.1 w/w % |

In the most preferred embodiment, the levels are as follows:

| | | |
|---|---|---|
| HM Pectin | about | 0.8 w/w % |
| CMC | about | 0.015 w/w % |
| MCC | about | 0.085 w/w % |

In the nutritionally complete child product, the stabilizer is present at from about 0.5 to about 1.5% by weight, more preferably from about 0.5 to 1.0% by weight, and consists of only high methoxy pectin.

In a preferred embodiment of the invention, the HM pectin is mixed with a source of carbohydrate and nutrients (i.e., calcium, trace and ultra trace minerals) to form an aqueous carbohydrate/mineral slurry. The carbohydrate/mineral slurry is then combined with the protein slurry and the oil blend and further processed. To realize the full benefit of the invention disclosed herein, the pectins (e.g., GENU and Slendid 200) should be added first and it should be agitated at a rate and for a time sufficient to properly hydrate the HM pectin. Minerals and carbohydrates are added once the pectins are fully hydrated.

## C. Calcium Source

One important aspect of the low pH beverage of this invention is that it can, in relatively little volume, deliver significant levels of bioavailable calcium. It is, in part, the high concentration of soluble $Ca^{2+}$ ions that causes some of the physical instability, sedimentation and mouthfeel problems of a nutricut rich, low pH beverage.

In general, any known source of $Ca^{2+}$, that does not adversely affect the product, can be utilized in this invention. Typically, at least one source will be selected from calcium glycerophosphate, calcium citrate, calcium phosphate tribasic and calcium lactate. Preferably, calcium glycerophosphate and calcium citrate in about a 40:60 weight ratio is used as they are more soluble than other sources of calcium and also have a less chalky mouthfeel. In one embodiment of the invention, the source of bioavailable calcium is a 40:60 mixture of calcium glycerophosphate and calcium citrate. Other embodiments include calcium sources such as calcium lactate and calcium gluconate in combination with calcium citrate. The amount of the calcium source in the beverage can range from about 0.05–1.0% by weight. As used in this application, any reference to an amount of calcium refers to the amount elemental calcium that should be utilized and not the amount of the calcium salt. Preferably, the level of calcium results in 25–50% of the RDI for the average adult in a volume of approximately 250 ml of the beverage. In the nutritionally complete child product, the source of calcium is preferably calcium phosphate tribasic at a concentration of 0.0–0.5% by weight (elemental calcium).

As is described in greater detail in Example XIII, it was discovered that calcium citrate malate was not compatible in an acidic solution containing proteins. The calcium citrate malate caused the proteins to gel, thereby rendering the beverage unsuitable for consumption. This was a most unexpected finding since calcium citrate malate is routinely added to orange juice which has an acidic pH.

If desired, sources of boron may be added to the nutritional to enhance the absorption of calcium. The amount of boron can vary widely but will typically range from about 500 micrograms to about 600 micrograms per single serving. Sodium borate is currently the preferred source of boron.

D. Acidulants

The present invention typically employs a food acid, or acidulant, to adjust the pH of the final nutritional product to a range of from about 3.0–4.6, more preferably from about 4.0–4.4 and most preferably from about 4.1–4.3. However, such a food acid is not required as long as other ingredients contained within the formulation lower the pH (i.e., fruit juices, flavorings, etc.).

Typically, the food acid is added in an amount ranging from about 0.1% to about 10%, more preferably about 0.2%–5% and most preferably from about 0.3% to about 2% by weight of the beverage. It is also within the scope of this invention to increase the level of the food acid up to about 1% by buffering the pH with buffering salts. In general, any known acidification agent can be used in this invention (i.e., lactic acid-producing organisms, mineral acids and food grade acids). Preferably, the acidulants for this invention are food grade acids selected from citric acid, phosphoric acid, tartaric acid, lactic acid, malic acid, gluconо delta lactone and mixtures thereof. The inventors herein evaluated a number of acidifying systems based on the resulting organoleptic properties imparted to the beverage. It was determined that in the inventive beverage, which contains high levels of proteins and minerals which act as buffering agents, a significant amount of acid is typically required to lower the pH. It was determined that a mixture of citric acid and phosphoric acid solutions (at about 50% by weight concentration) at about a 70:30 weight ratio is preferred.

E. Emulsifier System

Optionally, an emulsifier can be added to the low pH beverage. If utilized, the emulsifier system is preferably at least one component selected from the group consisting of lecithin, monoglycerides, diglycerides, diacetyl tartaric acid esters of mono- and diglycerides, and mixtures thereof. Of the various food emulsifiers currently available, only three (3) have GRAS (Generally regarded as safe, FDA) status: lecithin, mono-diglycerides and diacetyl tartaric acid esters of mono- and diglycerides. The preferred emulsifier system is soy lecithin alone or in combination with diacetyl tartaric acids and esters of mono- and diglycerides

Lecithin is an amphoteric surfactant that will be positively or negatively charged, depending on the pH of the environment. Mono-diglycerides are non-ionic surfactants. Diacetyl tartaric acid esters of mono-diglycerides are ionics with a very hydrophilic component attached. These hydrophilic components are carboxylic acids and can act as such or as the respective anions. They work by imparting a negative charge to the fat globules in the matrix, thus causing them to electrostatically repel each other so that no flocculation or coalescence occurs. Panodan® is a brand of diacetyltartaric acid esters of mono- and diglycerides made from edible, refined vegetable fat by Danisco Ingredients Company Products, Inc. of Kansas, USA. Soy lecithin alone is the preferred emulsifier due to its lower melting point and ease of incorporation into the oil blend. The amount of the emulsifier is chosen to suit the particular beverage and generally ranges from about 0.01–5.0% by weight of the liquid nutritional product. The nutritionally complete child product preferably uses a mixture of lecithin, monoglycerides and diglycerides as the emulsification system at a concentration of about 0.1–0.5% by weight.

F. Antioxidant System

The beverage of this invention may also optionally contain an antioxidant system at a concentration from about 0.001–5% by weight to prevent the degradation of the unsaturated lipid component. Protection of the unsaturated lipid is especially important when the beverage is in powdered form. At low pH, the triglycerides in the oils can hydrolyze and release free fatty acids which are prone to oxidation and heat can accelerate this reaction. Protection of the lipid component is especially important when soy oil, canola oil and/or marine oil are utilized in the beverage due to their degree of unsaturation. The antioxidant system employed herein uses a system of naturally occurring ingredients that comprise mixed tocopherols and ascorbyl palmitate. In a second embodiment, the three-part antioxidant system comprises ascorbyl palmitate, mixed tocopherols and citrate. The nutritionally complete child product preferably contains from about 0.1–3% by weight of the three-part system.

G. Carbohydrates

The quantity of carbohydrate that is utilized in these low pH products can vary widely. The amount of carbohydrate will typically range from about 1–30%, more typically about 1–25% and most preferably about 5–20%, by weight.

The carbohydrates may be any of the digestible carbohydrates such as dextrose, lactose, fructose, sucrose, maltose, corn starch, hydrolysed corn starch, maltodextrin, glucose polymers, corn syrup solids, oligosaccharides, high saccharides, high fructose corn syrup or mixtures thereof, depending on usage.

If desired, indigestible carbohydrates may optionally be incorporated into the formula. One such example is an indigestible oligosaccharide such as fructooligosaccharide. Fibers, both soluble and insoluble may be incorporated into the beverages. Examples of such fibers include soy, oat, pea, beet, cellulose, corn, gum arabic, sodium carboxymethylcellulose, guar gum, citrus pectin, barley and psylium.

In the nutritionally complete child product, the carbohydrate is at 5–15% by weight and is preferably hydrolyzed corn starch with a DE (dextrose equivalent) of 10 to 25. A hydrolyzed carbohydrate is desirable since it keeps the osmolarity down and is easily digested.

H. Edible Oils

The lipids or edible oils useful in the beverage of the invention are those known to be consumable by a human. The quantity can vary widely depending upon the end use of the product. For example, if the product is intended to be suitable as a sole source of nutrition it will have a relatively high level of fat, so that a sufficient number of calories can be provided to the patient to prevent malnutrition. If the beverage is only intended as a supplement to provide calcium, proteins or vitamins, then it can be fat-free. The amount of oils and the types required to accomplish these results are well known to those skilled in the art. However as a general guideline, the beverages will contain from about 0–10% by weight of an edible oil.

In one embodiment of the invention, the edible oil component is a mixture comprising soy oil and marine oil (i.e., oil derived from fish, fungal and genetically engineered plants that contain high levels of n-3 and/or n-6 polyunsaturated fatty acids at a level of from about 0.5–10% by weight. In another embodiment, the inventive beverage uses a mixture of canola oil and high oleic safflower oil. In one embodiment of the invention for children, the oil blend comprises high oleic safflower oil, soy oil, and fractionated

coconut oil. The concentration of the edible oil in the child's product is preferably from about 4.0 to 6.0% by weight and should be a high oleic oil, as children need this fatty acid.

However numerous other oils or combinations of oils may be incorporated into the beverage. Examples of suitable oils include olive, borago, black currant seed, corn, marine oils, fungal oils, safflower, high oleic safflower, sunflower, high oleic sunflower, evening primrose, cottonseed, rice bran, grapeseed, flaxseed, garlic, peanuts, almonds, walnuts, wheat germ, egg, high oleic sunflower oil, and sesame.

## I. Vitamins and Minerals

Vitamins, minerals and other trace elements can be used to supplement the food composition and for purposes of total nutritional balance. These supplements can be varied as desired but are typically equal to the RDI or greater, based on 2,000 calories per day. In a preferred embodiment of the invention, at least 25% of the RDI for vitamins A, D, E and K are supplied in approximately 250 ml of the beverage as well as 25% of the RDI for calcium and selenium.

After numerous sources of magnesium were evaluated (e.g., magnesium carbonate, magnesium citrate, magnesium gluconate, magnesium hydroxide, magnesium sulfate and the like), it was determined that about a 30:70 weight ratio of magnesium phosphate dibasic and magnesium chloride is preferred for the inventive beverage. This mixture is preferred due to its clean taste and buffering capacity. Also preferred is the use of magnesium gluconate as the source of magnesium due to its non-bitter taste. Minerals with a low buffering capacity are desired so that less acid is required when bringing down the pH of the beverage to below 4.2.

In the nutritionally complete child beverage, it is preferred that it contain at least 100% of the RDI for children for protein, calcium, vitamin C, thiamine, iron, vitamin $B_{6}$, folic acid, vitamin $B_{12}$, zinc, vitamin D, vitamin E and vitamin K in approximately one liter of the beverage.

## J. Other Ingredients

The beverage of this invention can include a fruit juice component, especially for the child beverage. The fruit juice can be any citrus juice, non-citrus juice or mixtures thereof which are known for use in edible products. Examples of such fruit juices include, but are not limited to, non-citrus juices such as apple juice, grape juice, pear juice, nectarine juice, currant juice, raspberry juice, strawberry juice, kiwi juice, watermelon juice, cherry juice, cranberry juice and mixtures thereof. Representative of the citrus juices useful in the inventive beverage include orange juice, lemon juice, lime juice, grapefruit juice, tangerine juice and mixtures thereof. Apple and pear juice is especially preferred for use herein.

The beverages prepared according to the present invention typically contain about 0% to about 50% fruit juice, preferably from about 3 to about 25% fruit juice, most preferably from about 3 to about 15% fruit juice. The fruit juice may be incorporated into the beverage as a puree, comminute or as a single strength or concentrated juice. Most preferred is the incorporation of a fruit juice as a concentrate with a solids content of between 20 and 60% by weight. The beverage of the present invention may also employ other flavors, alone or in combination, with the fruit juice.

Conventional coloring agents, such as approved colors, may be used as well as the conventional antioxidants, such as BHT and BHA. In one preferred embodiment L-cysteine, an amino acid, is added to protect the vitamin C from degradation. Typical levels of L-cysteine can range from 0.001 to 0.1% by weight.

Through the work of the inventors, it has been determined that the inclusion of the free amino acid L-cysteine in the inventive formula is preferred as it provides for acceptable visual appearance of the product and improves the stability of vitamin C in the product. L-cysteine acts as a reducing agent to inhibit the oxidation of vitamin C. It has been found that without the addition of sufficient levels of L-cysteine, oxidation of the vitamin C caused discoloration of the product (taupe/coffee color) after about one month of room temperature storage, with increasing discoloration over time. This problem can also be overcome by elimination of oxygen from the headspace of the container. This is not acceptable in a fruit flavor product as it decreases the consumers compliance. The minimum level of L-cysteine should be used to stabilize the vitamin C as excess levels will impart a sulfur or chemical-like taste and aroma to the product. The actual optimal level is thus dependent upon the level of vitamin C incorporated into the product.

The beverage of this invention may comprise from about 45 to about 95% water by weight. It should be understood that when the beverage according to the invention is in powdered form, water content is typically in the range of less than 5% and more preferably below 3%. The ready-to-feed beverage preferably comprises from about 60 to about 90% water; most preferably from about 75 to about 85% water. The water may be added directly, or it may be provided from alternative sources such as fruit juices, flavorings, etc. Soy bran, rice bran or other fiber polysaccharides or sources of fiber can be included in the beverage according to this invention as is known in the art.

The beverage of the present invention may also employ a sweetener. Representative of the sweeteners useful in this invention include maltose, sucrose, glucose, fructose, invert sugars and mixtures thereof, which also form part of the carbohydrate component. The sugars may be incorporated into the beverage in solid or liquid form but are typically incorporated as a syrup such as a high fructose corn syrup. It should be understood that the other components of the beverage, such as the fruit juice component, optional flavors and the like, may provide a sweetening component to the beverage. Sweeteners comprise from about 0.1 to about 20% by weight, more preferably from about 6 to about 14% by weight of the inventive beverage. The sweeteners for use in the beverage may be sucrose, fructose and mixtures thereof. The total carbohydrate component, including sweeteners, can range from 1–20 weight %, more preferably from 5–15 weight %.

Optionally, artificial or non-caloric sweeteners can be used in the present invention alone or in combination with nutritive sweeteners. Examples of the artificial or non-caloric sweeteners include, for example, saccharin, cyclamates, acetosulfan-K, polydextrose, L-aspartame, sucralose, low alkyl ester sweeteners and the like. Artificial or non-caloric sweeteners, if used, are typically employed in an amount ranging from about 0.005 to about 1% by weight. More preferably, from about 0.005 to about 0.1% by weight of the beverage. In one embodiment of the invention the combined use of a caloric and non-caloric sweeteners is contemplated.

The beverage of the present invention may also, optionally, employ a preservative. Any food grade preservative can be used and suitable preservatives include sorbic acid, benzoic acid, alkali metal salts thereof and mixtures thereof. Preferred preservatives include sorbic acid, potassium sorbate, potassium benzoate, sodium benzoate, sodium sorbate and mixtures thereof. The preservative is typically present in a total amount ranging from about 0.04 to about 0.2% by weight. More preferably, the preservative is in the range from about 0.04 to about 0.1% by weight. In a preferred embodiment, the beverage contains about 0.03% by weight potassium sorbate and about 0.06% by weight potassium benzoate.

As mentioned above, the beverages according to the invention are fortified with various vitamins and minerals. The level of the vitamins and minerals contained within the beverage will preferably supply at least 100% of the U.S. RDI for vitamins A, B, C, D, K and the minerals calcium, iron, phosphorus and manganese in approximately 1000 ml of the low pH beverage. This may he expressed alternatively as "the beverage will preferably supply at least 25% of the U.S. RDI for vitamins A, B, C, D, K and the minerals calcium, iron, phosphorus and manganese in a 250 ml serving of the low pH beverage, which is approximately 250 ml. Approximately 250 ml is meant to convey an amount an adult can easily consume in one setting, such as, for example, from 225–275 ml.

As mentioned previously, vitamin C is known to degrade via oxidation at low pH values and thus, it is preferable to add the amino acid cysteine as a reducin agent. The level of cysteine should be about 2–15 weight % of the ascorbic acid added. In a preferred embodiment, the beverage contains from 30–50% of the RDI for vitamin C and the L-cysteine can range from 10 to 100 ppm. When about 30% of the RDI for vitamin C is used in the product, the level of L-cysteine can range from 20–40 ppm or 0.002 to 0.004% by weight.

The caloric content of the inventive beverage can he adjusted to any desired level up to about 3 calories per cubic centimeter. The caloric density of the beverage can vary widely. Typically their density will range from about 0.5 kcal per ml up to about 2.0 kcal per ml, and more preferably no greater than about 1.5 kcal. per ml. Most preferred is a caloric density of about 0.8–1.2 kilocalories per ml. The osmolarity of the beverage can range from 250–650, but preferably is in the range of 275–550 mOsm.

## Process Steps

The beverage according to the invention can he prepared using conventional equipment and process technology known to those skilled in the art. The incorporation of the pectin components can be accomplished in two (2) general manners. The first approach to pectin incorporation comprises the dry blending of the pectin into a portion of the carbohydrate (i.e., sucrose) at a weight ratio of about 1:5, pectin to carbohydrate. The pectin/carbohydrate dry blend is then added to hot water with agitation. The remaining portion of the carbohydrate is then added after the pectin has become fully hydrated. The minerals are then added to the pectin/carhohydrate solution to form the carhohydrate/mineral slurry.

A more preferred process comprises mixing the pectin with water under high shear mixing and at a temperature of hetween 65° C. and 75° C., more preferably between 65° C. and 71° C. The pectin solution should not exceed about 10% pectin by weight. After mixing for about 10 minutes, the source of calcium is added to the solution following by addition of the major minerals, trace/ultra trace minerals and the carbohydrate, thus forming the carhohydrate/mineral slurry.

In yet another preferred embodiment, especially for the pediatric product, it has been found useful to combine the protein and the pectin and subject the mixture to homogenization prior to combination with other beverage components. It has heen found that a homogenization of the pectin protein mixture at a pressure of at least 1,000 psig is satisfactory.

An oil blend is prepared by mixing the edihle oil with the emulsifier system, vitamins A, D, E and K, ascorhyl palmitate and mixed tocopherols.

The protein slurry is prepared hy mixing the source of protein with a portion of the product water under agitation to a protein content of about 5% by weight.

The protein slurry is then combined with the carbohydrate/mineral slurry and subsequently with the oil hlend to form a protein/carhohydrate/mineral oil mixture. This mixture is then preferably subjected to a two-stage homogenization wherein the second stage is from 3.5–4.1 MPa (500–600 psig) and the first stage pressure is from 17.2 to 27 MPa (2,500–4,000 psig). The homogenized hlend is then acidified with an edible acid and/or fruit juice to a pH of about 3.0–4.6. A preferred edible acid comprises a mixture of phosphoric acid and citric acid at a weight ratio of about 1:3. At this point, flavor, colors, vitamins, water, folic acid, cysteine and ascorhic acid may be added to the acidified mixture. The pH of the mixture is finally adjusted to a pH of about 4.0 to 4.35 and again homogenized at a pressure of at least 17 MPa after sterilization to form an aqueous food product. If the product is again subjected to farther heat treatment, for example in aseptic packaging, an additional homogenization at a minimum of 6.8 MPa (1,000 psig), preferahly 10.3 MPa (1,500 psig) should he conducted prior to the filling of containers with product.

In this process, it is important that the carhohydrate/mineral slurry he added to the protein under conditions of high shear so as to assure that the protein and stahilizer particles have an average particle size of less than about 1 micron, preferably less than about 0.8 microns and most preferably less than about 0.5 microns. As used herein, the term "high shear" refers to conditions exemplified, but not limited to, a homogenizer operating at about 4,000/500 psig (27/3.5 MPa) and a high shear mixer with a batch turn-over rate of 1–5 minutes. Those skilled in the art will readily appreciate the parameters under which the homogenizer must he operated to achieve the recited pressures. Without heing hound to any theory, it is postulated that the homogenization prior to the addition of the edible acid and/or fruit juice allows for the proper interaction between the pectin and the proteins. Another important aspect is that a second homogenization occurs subsequent to the acidification with the acid hlend and preferably after a final heat treatment.

The temperature range to which the beverage is subjected to during processing is not critical, however it is highly advantageous to maintain the process subsequent to the first homogenization between 10° C. and 40° C. Subsequent to the acidification and second homogenization of the beverage, the product is held under low shear conditions.

The heverage according to the present invention has a pH ranging from about 3.0 to about 4.6, preferably from about 4.0 to about 4.6 and most preferably from about 4.0 to about 4.35. The hevcrage exhibits little or no sedimentation and any sediment that does form is readily dispersed upon mild shaking. This physical stability lasts for at least 12 months despite the high levels of protein, calcium, and other minerals. The heverages described herein are pleasant tasting, smooth textured and may or may not he carbonated. The beverage according to the invention may also be dried and supplied in the form of a powder which can be readily reconstituted with water or juices.

As used herein, any use of the term "about" should be construed as referring to both of the number specified in any range. Any reference to a range should be considered as providing support for any subset within that range. For example, a range of 1–10 should be considered to provide support for a range of 7–9, 3–6, 2–8, etc. Any reference to a single serving is referring to a volume that can be consumed by an adult in one setting, approximately 250 ml(225 ml–275 ml), and more preferahly about 237 ml.

The following Examples depict the presently preferred embodiments of the invention for the purposes of illustrating the practice thereof and do not, in any way, limit the scope of the invention.

EXAMPLE I

Protein System

The materials employed in the process of preparing the inventive beverage include milk components, food acids, as well as other ingredients such as a source of calcium, trace and ultra trace minerals. The protein system or source of amino nitrogen utilized in the low pH beverage of this invention was carefully selected based on the sensory characteristics of the protein at low pH. Over fifty (50) proteins or protein combinations that included casein, whey, total milk proteins, pea and soy were examined in both 5% by weight solutions and in a low pH model system composed of 5% carbohydrate, 5% protein, 0.6% pectin, citric and lactic acids. The solutions ranged from clear to cloudy and opaque with sediment, with whey separation occurring in some solutions. The taste of the various protein systems ranged from milky to bitter, burnt and brothy. Proteins were excluded from further consideration due to unacceptable flavor, instability and availability. Preferred proteins were then evaluated in a complete formulation similar to that set forth in Table 6 and screened for sensory characteristics. The screening indicated that a protein system containing 70–80% sodium caseinate combined with 28–30 weight % whey protein was the most preferred. An additional protein system found to be useful in the present invention included milk protein isolate in combination with calcium or sodium caseinate. In the children's beverage according to this invention, the use of total milk protein is preferred, especially if subjected to terminal sterilization.

EXAMPLE II

Pectin Evaluation

Numerous types of pectin are known and used in the food industry in products such as jams, jellies, ice creams, fat substitutes and the like. This experiment was conducted to evaluate various high methoxyl (HM) citrus pectins for the stabilization of the high protein content, low pH beverage of this invention. A number of pectins from various suppliers were initially screened for their ability to stabilize proteins at low pH. Those pectins that resulted in a stable product after a high temperature short time (HTST) treatment in either hot fill or aseptic packaging were further evaluated.

Four (4) pectin candidates were selected for evaluation of their mouthfeel and viscosity increasing properties. Three (3) pectins from the Danisco Ingredients Co. of USA known as RS400, RS450 and AM491 were compared to Hercules JMJ. Table 3 sets forth the level of pectin addition, the sensory comments and the initial viscosity of the product.

TABLE 3

| Sample # | Pectin Type (manufacturer-code) | Pectin Level (% by weight) | Sensory Comments* | Initial Viscosity (cps) |
|---|---|---|---|---|
| 1 | Danisco RS400 | 0.75 | Skim milk-like thickness, chalky, drying | 34 |
| 2 | Danisco RS450 | 0.75 | Twice as thick as Sample #1, drying, chalky | 57 |
| 3 | Danisco AM491 | 0.94 | Creamy, drying, not as thick | 35 |
| 4 | Hercules JMJ | 0.6 | Cream, cool whip-like | 17 |

Light micrographs of each Sample were obtained to evaluate protein aggregation. Samples 1–3 showed large aggregates that represent a physically unstable product. The light micrograph of Sample 4 showed good stabilization of the proteins as indicated by small aggregates throughout the product.

The level of pectin required in a product to assure physical stability depends on the amount of protein present, pH, soluble solids content, fat content, ionic concentration, titratable acidity, length and severity of heat treatments and projected shelf life. Experiments were conducted to determine the optimal concentration of Hercules-JMJ pectin in the inventive beverage. Concentrations varied from 0.4–0.9 weight % of product or 11:1–5:1 protein to pectin weight ratios. The various levels of Hercules JMJ pectin were formulated into an adult beverage and viscosities were determined at 13 reciprocal seconds, using a Brookfield viscometer with a #1 spindle. The viscosity at 100 reciprocal seconds represents the shear during swallowing or mouthfeel. Table 4 sets forth the results of this experiment.

TABLE 4

| | JMJ Pectin Concentrations | | |
|---|---|---|---|
| Sample # | Pectin Level (weight %) | Viscosity (13 1/sec) | Viscosity (100 1/sec) |
| 5 | 0.6 | 10.6 | 7.9 |
| 6 | 0.75 | 20.7 | 15.2 |
| 7 | 0.8 | 9.8 | 12 |
| 8 | 0.9 | 22.1 | 17 |

An evaluation of this data indicates that JMJ pectin at a concentration of 0.8 weight % is optimal for the adult beverage of this invention. In an experiment using a child matrix of components, it was determined that a level of about 0.725 weight % is preferred.

EXAMPLE III

Stabilizer System

While pectin was shown in Example I to act as a protein stabilizer in low pH formulations, sediment still formed as the beverage contained high levels of protein and total solids. After about one month, the beverage of Example I with 0.6 weight % JMJ pectin, formed a sediment which attached to the bottom of the container and was very difficult to disperse. Analysis of sediment determined that it was composed of approximately 60% water, 5% fat, 20% protein with the remainder being carbohydrate (including pectin) and some minerals.

In this experiment, various stabilizers were used in conjunction with JMJ pectin at 0.6 weight % levels. Table 5 sets forth the system used in each Sample and resulting viscosities of the adult beverage at six (6) weeks of age.

TABLE 5

| Sample # | 0.6 weight % JMJ Pectin Plus Others: Additional Stabilizer weight % (unless other stated) | Viscosity* 13 1/sec Carri-Med (cps) | Viscosity* 100 1/sec Carri-Med (cps) |
|---|---|---|---|
| 9 | Slendid 200 0.2% Avicel 1,000 ppm | 79 | 36.8 |
| 10 | Slendid 200 0.3% Avicel 1,000 ppm | 155 | 58.6 |
| 11 | Slendid 200 0.25% | 147 | 55.7 |
| 12 | Gellan Gum 75 ppm** Avicel 1,000 ppm | 86 | 36.5 |

*After six (6) weeks of storage at room temperature

**Gellan Gum is multi-functional polysaccharide produced by the microorganism *Pseudomonas elodea* and is distributed by the Merck & Co., Inc. of Whitehouse Station, N.J.; Kelco Division-USA.

At two and one half (2½) months, the experimental beverages evidenced no sediment on the container bottoms after a 2–3 second shake. One unique characteristic of these stabilizer systems is their thixotropic character wherein shear breaks down structure and the beverage becomes thinner. Samples 5–8 in Example II exhibited Newtonian behavior in that the viscosity was virtually the same regardless of shear rate. The data contained in Table 5 indicates that at low shear (13 reciprocal seconds) viscosities are high (i.e., 79–155 cps). In contrast, at 100 reciprocal seconds (shear rate of swallowing) the beverage is much thinner (i.e., 36–58 cps).

To evaluate the effect that this increased structure would have on consumer acceptability, a panel of fifty-three (53) professional tasters were asked to evaluate Samples 9 and 10, and compare them to three (3) commercially available products from the Ross Products Division of Abbott Laboratories, Columbus, Ohio; Ensures®, Ensure® Light and Ensure Plus®. The Ensure® product line provides complete, balanced nutrition in two (2) quarts (2000 calories in about 2 liters) and has a pH of about 6.8–7.1. Ensure Plus and Samples 9 and 10 were judged to have the same thickness, while Ensure and Ensure Light were significantly thinner. On thickness preference, all samples, except Ensure Light, were equally preferred. Ensure Light was significantly less preferred.

Additional beverages were made using only pectin as the stabilizer system, using the same methodology as the sample immediately above. The only change was that the pectin concentration was increased to 0.8% of JMJ pectin. The viscosity of theses samples were evaluated at the times indicated in Table 5B in the same manner as Tables 4 and 5. In addition to evaluating viscosity, physical stability was also evaluated. The following factors were reviewed:

(1) Bound and unbound sediment; and

(2) Formation of whey layer (clear layer at top of container). The physical stability was evaluated at one month, three months, six months, nine months and ten months. After ten months, these samples did not have a sediment problem and would be acceptable for commercial sale. The following viscosity measures were obtained.

TABLE 5B

| | 0.8% high-methoxy pectin, no additional Stabilizer | Viscosity Brookfield 13 1/sec, cps | Viscosity 13 1/sec Carri-Med, cps* | Viscosity 100 1/sec Carri-Med, cps** |
|---|---|---|---|---|
| 1 month | | 44.6 | NT | NT |
| 3 months | | 49.7 | NT | NT |
| 6 months | | 47.7 | NT | NT |
| 9 months | | 50.9 | NT | NT |
| 10 months | | NT | 44 | 32 |

*Equivalent to Brookfield viscosity

*Equivalent to Swellowing Shear Rate

As demonstrated above, pectin alone in sufficient concentration can be used to stabilize low pH beverages.

## EXAMPLE 1V

### Production of the Low pH Beverage According to the Invention—Adult Version

In this experiment, a 1,000 Kg batch of a peaches and cream flavored beverage according to the present invention was prepared using the bill of materials set forth in Table 6.

TABLE 6

Bill of Materials for PEACHES AND CREAM Flavored Low pH Beverage Yield 1,000 kg Batch

| INGREDIENT NAME | AMOUNT (Kg/1,000 kg) |
|---|---|
| Ingredient Water | ~780.1 |
| Sucrose | 79.88 |
| Maltodextrin (Lodex 15) | 44.95 |
| Milk Protein Isolate | 31.62 |
| Calcium Caseinate (Miprodan 505) | 16.56 |
| High Oleic Safflower Oil | 8.80 |
| Citric Acid | 6.64 |
| Pectin GBNU JMJ 100 | 6.00 |
| Phosphoric Acid (75%) | 3.80 |
| Canola Oil | 3.77 |
| Potassium Citrate | 3.12 |
| Sodium Citrate | 2.34 |
| Magnesium Chloride | 2.32 |
| Tastemaker NA Peaches & Cream 356263 | 2.00 |
| Slendid L200 (pectin) | 2.0 |
| Avicel CI-611 | 1.0 |
| Magnesium Phosphate Dibasic | 0.85 |
| Ascorbic Acid | 0.75 |
| Potassium Benzoate | 0.6 |
| Choline Chloride | 0.53 |
| Soy Lecithin | 0.52 |
| UTMITM Premix* | 0.468 |
| Calcium Citrate | 0.36 |
| Calcium Glycerophosphate | 0.34 |
| Potassium Sorbate | 0.3 |
| Sodium Chloride | 0.21 |
| Oil Soluble Vitamin Premix | 0.1025 |
| Water Soluble Vitamin Premix | 0.07672 |
| Ascorbyl Palmitate | 0.01585 |
| FD&C Yellow #6 | 0.012 |
| L-Cysteine | 0.01125 |
| Vitamin A Palmitate | 0.00948 |
| Tenox GT-2 (Mixed Tocopherols) | 0.00264 |
| Folic Acid | 0.002346 |
| FD&C Red #40 | 0.002 |
| Potassium Iodide | 0.00023 |

*Ultratrace mineral and trace mineral premix

The manufacturing process used in this Example can be used, with minor modifications to make various embodiments of the present invention. The manufacturing process consisted of seven (7) steps which were as follows:

1. Preparation of the Oil Blend

The required amounts of high oleic safflower, canola oils and lecithin, and the emulsifier were blended and heated to 90–120° F. (30–49° C.). The vitamin A palmitate and the vitamin D, E, and K premix were then added. The mixed tocopherols and ascorbyl palmitate, which were used to prevent lipid oxidation at the low pH of the product, were also added. This oil blend was held under gentle agitation at about 35° C. until use.

2. Preparation of the Carbohydrate/Mineral Slurry

The carbohydrate/mineral slurry was made by adding potassium benzoate and potassium sorbate to water, heated to about 65–71° C. and agitating the solution until the preservatives were fully dissolved. The GENU JMJ and Slendid 200 were then directly dumped into the water and the mixture was agitated for about thirty (30) minutes to ensure proper hydration of the pectins. Top to bottom tank mixing is required to properly hydrate the pectins since they float until hydrated. Upon the hydration of the pectins, the following ingredients were, added: Avicel CL-611, sodium citrate, potassium-citrate, calcium glycerophosphate, calcium citrate, trace/ultratrace minerals premix, magnesium phosphate dibasic and potassium iodide. After sufficient agitation to properly disperse/dissolve the minerals, the maltodextrin and sucrose were then added. The carbohydrate/mineral slurry was held at 60–71° C. until used. The solid content of the slurry is approximately 35% by weight.

3. Protein Triblending

The calcium caseinate and milk protein isolate were triblended with water into the blend tank at 65–71° C.

4. Blending and Processing

The carbohydrate/mineral slurry and the oil blend were added to the blend tank and mixed vigorously. At this point, the pH of the mixture was about 6.6. The blend was then heated to about 68–80° C., deaerated, homogenized through a single stage homogenizer (900–1,100 psig), heated to about 79° C., homogenized through a two stage homogenizer at 4,000/500 psig, passed through a holding tube to assure a 73–85° C. heat treatment for about sixteen (16) seconds. The blend was then cooled to about 1.6–7° C. and held at that temperature until further use. The blend at this time had a pH of about 6.7.

5. Acidification

A mixture of citric acid and phosphoric acid, 70:30 weight %, was prepared and added to the batch so that a pH ranging from 4.0–4.35 was achieved.

6. Standardization

Additional dilution water was added to the batch and thereafter the peaches and cream flavor and coloring were added. A solution containing the water soluble vitamin premix and choline chloride was then added. Thereafter, an ascorbic acid solution containing ascorbic acid and L-cysteine, was added. Finally a folic acid solution was added to the batch.

7. Heat Process and Aseptic Filling

The final product blend was preheated to 36–65° C. and homogenized through a single stage homogenizer at 2,900–3,000 psig (20–20.7 MPa). The product was then heated to 102–104° C. and held there for seventeen (17) to eighteen (18) seconds. The final product blend was then cooled to 65–82° C. and passed through a remote homogenizer block at 1,100–1,500 psig (7.6–10.3 MPa) product. The product was finally cooled to about 21° C. and pumped the filler heads of the filling machine using aseptic processing technology.

The low pH beverage of the present invention is capable of providing refreshing fruit flavors in contrast to the old milkshake-type products. In addition to the peaches and cream flavor, flavors such as lemon cream, raspberry cream and pina colada were manufactured. A tasting panel found all products to be very acceptable with the peaches and cream and pina colada flavors most well received.

EXAMPLE V

Comparative

This experiment was conducted to evaluate the technology disclosed by Connolly in U.S. Pat. No. 5,409,725 which uses a reaction between protein and galactomannan to achieve protein stability in a low pH nutritional beverage.

Six (6) Samples were produced using a base formulation characterized in Table 7.

TABLE 7

Base Formulation for Comparatives Per 8 oz (231 ml) Serving

| COMPONENT | VALUE |
|---|---|
| Kcal | 145 |
| Carbohydrate, g | 25 |
| Protein, g | 9 |
| Fat, g | 1 |
| Kcal from Carbohydrate, % | 69 |
| Kcal from Protein, % | 25 |
| Kcal from Fat, % | 6 |
| Calcium, % RDI | 35–50 |
| Phosphorus, % RDI | 17.5–25 |
| Magnesium, % RDI | 43–63 |
| Vitamin D, % RDI | 30 |
| Vitamin C, % RDI | 100 |
| Vitamin B6, % RDI | 50 |
| Vitamin K, mcg | 330 |
| Folic Acid, %RDI | 50 |
| Zinc, % RDI | 35 |
| Copper, % RDI | 35 |
| Manganese (magnesium sulfate), mg | 2.5 |
| Sodium, mg | 100–200 |
| Boron, mg | 1–3 |

50% by weight of the protein was from calcium caseinate (Miprodan 505 from MD Foods of Denmark) and 50% by weight from milk protein isolate from Kerry Ingredients of Wisconsin. The carbohydrate was a 60:40 weight ratio of maltodextrin (Lodex 15)to sucrose. The source of calcium was a 50:50 weight ratio of calcium glycerophosphate and calcium citrate. The pH of the products were adjusted to a a 50:50 weight ratio blend of 25% citric and lactic acids.

The Samples varied in the type and amount of stabilizer system used as set forth in Table 8.

TABLE 8

Stabilizing Systems

| SAMPLE # | Variable + Supplier (concentration in weight %) |
|---|---|
| 13 | Control MaxPectin from Grinstead (0.006%) |
| 14 | Locust Bean Gum (LBG)/Guar Gum Blend CC427 from Contentinal Colloids (0.0035%) |

TABLE 8-continued

| SAMPLE # | Stabilizing Systems<br>Variable + Supplier<br>(concentration in weight %) |
|---|---|
| 15 | Low Viscosity LBG SG 14 from AEP Colloids (0.035%) |
| 16 | Jaguar 11220 Function enhanced Guar Gum from Rhone Poulenc (0.0035%) |
| 17 | High Viscosity LBG 100 from Rhone Poulenc (0.0035%) |
| 18 | LBG SG-14 (0.0035%) and MaxPectin (0.0025%) |

In accordance with U.S. Pat. No. 5,409,725, protein stability is achieved by subjecting an aqueous suspension of protein and galactomannan to conditions sufficient to promote chemical reaction between the protein and the galactomannan, forming an aqueous glycoprotein. The galactomannans recommended in the '725 patent include Locust Bean Gum (LBG) and Guar Gum. In this experiment, low viscosity (<3,000 cps) and high viscosity (>3,000 cps) LBG were evaluated alone or in combination with guar gum or pectin. Guar gum was also tested as the sole stabilizer. Three (3) suppliers were used: AEP Colloids of Ballston Spa, N.Y.; Continental Colloids of West Chicago, Ill.; and Rhone Poulenc of Cranbary, N.J.

Experimental products were manufactured as follows: An oil blend containing 40% high oleic safflower oil, 40% canola oil and 20% corn oil was heated to 43–49° C. and the oil soluble vitamins and β-carotene were then-added. A carbohydrate slurry was prepared by combining water, maltodextrin, and sucrose and heating to 43–63° C. A protein/gum blend was made by dissolving the protein sources and gums in water and holding for twenty (20) minutes at 66° C. The three (3) slurries were then blended and process at their inherent pH (~6.2–6.7). Processing conditions were:

| | |
|---|---|
| Homogenization: | 3,900–4,100/500 psig |
| Temperature: | 74–77° C. |
| Time: | 16 seconds |

A mineral slurry containing calcium, magnesium, sodium, potassium and chloride sources was prepared and added. The pH was then lowered to 4.0–4.2 with citric and lactic acids. Water soluble vitamins and final water were added and the final blend was submitted to a final heat process under the following conditions:

| | |
|---|---|
| Homogenization: | 2,500/500 psig |
| Temperature: | 210° F. |
| Time: | 10 seconds |

Product was filled at temperature in glass bottles, capped, inverted and held for one (1) minute. After one minute, bottles were cooled in an ice water bath. In addition, several bottles were retort sterilized to determine if the stabilized proteins could survive a more severe heat treatment.

The teachings of U.S. Pat. No. 5,409,725 were followed during the manufacture of experimental Samples 13–18. To promote chemical reaction between the protein and the various gums, the patent recommends holding the aqueous blend at 45–87° C. for 5–90 minutes. The protein/gum blend in these experiments were held at 66° C. for 20 minutes. The protein to galactomannan ratio recommended in the patent ranges from 5:1–20:1. Ratios evaluated in this experiment were 5.3:1 for the pectin control and 9.1:1 for the guar gum and LBG variables. The patent claims the use of calcium sequestering agents such as EDTA, trisodium phosphate, trisodium citrate, disodium phosphate, sodium hexametaphosphate or an alkali metal salt of tripolyphosphate. In these experiments, no calcium sequestering agent was added as potassium citrate, sodium citrate and dipotassium phosphate were present as sources of major minerals in the product. In addition, the calcium salts used are calcium glycerophosphate and calcium citrate. Thus, there are considerable amounts of citrate and phosphate ions in the formula to sequester calcium. The acidifying agents used, citric and lactic acids, are also among the acids recommended in the patent. The pH range of the Samples were 4.0–4.2 which is within the range claimed in the patent (2.0–6.0).

At the neutral pH, all batches could be homogenized and heat processed. The highest back pressure was seen in Sample 18. This batch had both LBG and pectin at a 5.1:1 protein to gum ratio. During the second heat treatment, although the Samples containing LBG or guar gum made it though processing, upon cooling they become gelatinous-like and some of the protein curdled and precipitated out of solution. On the other hand, the product containing pectin (Sample 13) was smooth, non-gritty and low in viscosity.

Because of the high content of phosphoseryl residues, caseins bind polyvalent cations strongly, leading to charge neutralization, aggregation and eventually to precipitation. It is possible that the stabilization mechanism described in U.S. Pat. No. 5,409,725 is not effective in high protein and high mineral matrices such as the beverage of the present invention. Pectin stabilization appears to be an effective mechanism for the beverage of the present invention, even when submitted to retort sterilization Example VIII below, which uses terminal sterilization, supports this conclusion.

From this experiment, it was determined that the use of LBG and guar gum to stabilize intact proteins in the low pH beverage of the invention was not as effective as the use of pectin as the stabilizing agent. Samples containing the galactomannans did not survive processing or retort sterilization and curdled and phase separation occurred. In contrast, products containing pectin were smooth, non gritty and low in viscosity. Thus, there is no advantage in using the technology taught in U.S. Pat. No. 5,409,725 for products containing high levels of protein and polyvalent ions, specifically calcium and magnesium.

## EXAMPLE VI

### Production of the Low pH Beverage According to the Invention—Child Version

In this experiment, a 1,000 Kg batch of a beverage according to the invention, especially designed for children of 1 to 10 years of age was prepared using the bill of materials set forth in Table 9.

TABLE 9

Bill of Materials for Acidified Child's Beverage
Yield 1,000 Kg Batch

| INGREDIENT | AMOUNT (Kg/1,000 Kg) |
|---|---|
| Water | 804.92 |
| Sucrose | 70.790 |
| Hydrolyzed Corn Starch | 25.370 |
| Sodium Caseinate | 26.620 |
| High Oleic Safflower Oil | 23.480 |
| Soy Oil | 14.090 |

TABLE 9-continued

Bill of Materials for Acidified Child's Beverage
Yield 1,000 Kg Batch

| INGREDIENT | AMOUNT (Kg/1,000 Kg) |
|---|---|
| MCT Oil | 9.390 |
| Whey Protein Concentrate | 7.457 |
| Pectin | 7.250 |
| Micronized Tricalcium Phosphate | 2.700 |
| Citric Acid | 2.04 |
| Malic Acid | 2.04 |
| Phosphoric Acid | 2.04 |
| Magnesium Chloride | 1.765 |
| Potassium Citrate | 1.470 |
| Potassium Phosphate Dibasic | 0.994 |
| Potassium Benzoate | 0.600 |
| Soy Lecithin (Centrol CA) | 0.500 |
| Mono-Di Glycerides (Myverol) | 0.500 |
| Choline Chloride | 0.380 |
| Potassium Sorbate | 0.300 |
| Ascorbic Acid | 0.290 |
| m-Inositol | 0.100 |
| Trace Mineral Premix (including carrier) | 46.03 gms |
| Ferrous Sulfate | 20.4 gms |
| Zinc Sulfate | 16.8 gms |
| Manganese Sulfate | 1.47 gms |
| Copper Sulfate | 1.36 gms |
| Sodium Selenate | 36.13 mcg |
| Sodium Molybdate | 33.19 mcg |
| Taurine | 38.900 gms |
| Water Soluble Vitamin Premix (including carrier) | 35.850 gms |
| Niacinamide | 13.5 gms |
| d-Calcium Pantothonate | 8.7 gms |
| Thiamine Hydrochloride | 2.2 gms |
| Pyridoxine Hydrochloride | 2.1 gms |
| Riboflavin | 1.7 gms |
| Folic Acid | 301 mgs |
| Biotin | 262 mgs |
| Cyanocobalamin | 5.9 mgs |
| Oil Soluble Vitamin Premix (including carrier) | 22.270 gms |
| Vitamin D3 | 6.7 mgs |
| Vitamin E | 11.7 gms |
| Vitamin K | 21.5 mgs |
| L-Carnitine | 9.340 gms |
| Ascorbyl Palmitate | 7.26 gms |
| VitaminA Palmitate | 991 mgs |
| Mixed Tocopherols (lenox GT-2) | 1.4 gms |
| Potassium Iodide | 0.066 gms |

The manufacturing process described in Example IV was used to prepare the product.

## EXAMPLE VII

### Production of a Low pH Beverage with Juice—Child Version

In this experiment, a 1000 Kg batch of a beverage according to the invention which contained fruit juice was prepared using the bill of materials set forth in Table 10. The process for production was substantially identical to that used in Example IV except that the product was hot filled and not aseptically processed.

TABLE 10

Bill of Materials - Child Beverage with 20% Juice

| INGREDIENT | KG PER 1,000 KG |
|---|---|
| Water | 798.90 |
| Sucrose | 55.280 |
| Sodium Caseinate | 26.420 |
| Hydrolyzed Corn Starch | 25.470 |

TABLE 10-continued

Bill of Materials - Child Beverage with 20% Juice

| INGREDIENT | KG PER 1,000 KG |
|---|---|
| High Oleic Safflower Oil | 23.480 |
| Soy Oil | 14.090 |
| Apple Juice Concentrate (70.5 BRIX) | 11.2 |
| Pear Juice Concentrate (70.5 BRIX) | 11.2 |
| MCT Oil | 9.380 |
| Whey Protein Concentrate | 7.457 |
| Pectin | 7.250 |
| Citric Acid | 4.12 |
| Micronized Tricalcium Phosphate | 2.700 |
| Phosphoric Acid | 1.38 |
| Magnesium Chloride | 1.765 |
| Potassium Citrate | 1.072 |
| Potassium Phosphate Dibasic | 1.017 |
| Potassium Chloride | 0.901 |
| Potassium Benzoate | 0.600 |
| Soy Lecithin (Centrol CA) | 0.500 |
| Mono/Di Glycerides (Myverol) | 0.500 |
| Choline Chloride | 0.380 |
| Potassium Sorbate | 0.300 |
| Ascorbic Acid | 0.290 |
| m-Inositol | 0.100 |
| Trace Mineral Premix (including carrier) | 46.03 g |
| Ferrous Sulfate | 20.4 g |
| Zinc Sulfate | 16.8 g |
| Manganese Sulfate | 1.47 g |
| Copper Sulfate | 1.36 g |
| Sodium Selenate | 36.13 mcg |
| Sodium Molybdate | 33.19 mcg |
| Taurine | 38.90 g |
| Water Soluble Vitamin Premix | 35.85 g |
| Niacinamide | 13.50 g |
| d-Calcium Pantothenate | 8.7 g |
| Thiamine Hydrochloride | 2.2 g |
| Pyridoxine Hydrochloride | 2.1 g |
| Riboflavin | 1.7 g |
| Folic Acid | 30.1 mgs |
| Biotin | 262 mgs |
| Cyanocobalamin | 5.9 mgs |
| Oil Soluble Vitamin Premix | 22.7 g |
| Vitamin D3 | 6.7 mgs |
| Vitamin E | 11.7 g |
| Vitamin K | 21.5 mgs |
| L-Carnitine | 9.34 g |
| Ascorbyl Palmitate | 7.26 g |
| Vitamin APalmitate | 991 mgs |
| Potassium Iodide | 0.066 g |

## EXAMPLE VIII

### Production of Low pH Beverage for Child Version—Total Milk Protein

Two low pH beverages for children were prepared in this experiment. The bill of materials for both beverages was identical to that set forth in Table 8 (Example VI) except that the sodium caseinate and the whey protein was replaced with 32.15 kg of milk protein isolate which is also known as total milk protein. Two different sources of total milk protein were utilized; New Zealand Milk Products of Santa Rosa, Calif. and Kerry Ingredients of Beloit, Wis. The beverages were packaged in metal containers and subjected to terminal sterilization. After about one (1) week of storage at room temperature, the beverages were evaluated for protein stability, color, viscosity and flavor. When compared to the mixture of proteins in Example VI, (sodium caseinate and whey) the total milk protein from both suppliers was found to be superior in flavor and protein stability. The total milk protein also provided a lighter colored beverage. Thus, for the child version of this invention, the use of total milk protein is preferred.

An additional experiment was conducted wherein GENU® JM 150 was compared to GENU® JMJ at various concentrations in a child version of the present invention. Based on % sediment and particle size of protein, it was determined that GENU® JMJ at about 0.75% by weight produced the most satisfactory beverage.

## EXAMPLE IX

### Production of an Adult Beverage

In this experiment, a 1000 kilogram batch of an adult beverage having a caloric density of 1.5 kilocalorie (kcal) per ml is prepared using the procedure of Example IV. The product had the following composition. The calcium is provided by the protein sources. A single serving will provide at least 25% of RDI for calcium (per US standard).

TABLE 11

| Category | Ingredients | Amount (Kg) |
|---|---|---|
| Carbohydrates | Sucrose | 98.1 |
| | Liquid Corn Syrup | 83.7 |
| Proteins | Milk Protein Isolate or Yogurt | 43.2 |
| | Cultured Milk Protein Isolate | |
| | Calcium Caseinate | 22.5 |
| Lipids | High Oleic Sunflower Oil | 23.7 |
| | Canola Oil | 13.4 |
| | Corn Oil | 8.68 |
| Emulsifier | Lecithin | 1.45 |
| | Magnesium Chloride | 3.47 |
| | Sodium Chloride | 0.22 |
| | Sodium Citrate | 3.82 |
| | Potassium Citrate | 4.52 |
| | Trace/Ultratrace Minerals Premix | 0.25 |
| | Potassium Iodide | 0.0002 |
| Vitamins | Oil Soluble Vitamins Premix | 0.1 |
| | Beta Carotene | 0.01 |
| | Ascorbic Acid | 0.45 |
| | Water Soluble Vitamins Premix | 0.1 |
| Conditional Nutrient Stabilizers | Choline Chloride | 0.6 |
| | Pectin | 8 |
| | Slendid 200 (pectin) | 1.5 |
| | Avicel CL-611 | 3 |
| Antioxidants | Mixed Tocopherols | 0.0009 |
| | Ascorbyl palmitate | 0.0544 |
| Processing Aids | Citric Acid | 0 |
| | Phosphoric Acid (85%) | 2.32 |

## EXAMPLE X

### Production of an Adult Beverage

In this experiment, a 1000 kg batch of an adult beverage having a caloric density of 1.5 kcal. is prepared using the procedure of Example IV. The product had the following composition. The calcium is provided by the protein sources. A single serving will provide at least 25% of the RDI for calcium (per US standard)

TABLE 12

| Category | Ingredients | Amount (Kg) |
|---|---|---|
| Carbohydrates | Sucrose | 97.5 |
| | Liquid Corn Syrup | 81.2 |
| Proteins | Milk Protein Isolate or Yogurt | 47 |
| | Cultured Milk Protein Isolate | |
| | Calcium Caseinate | 12.3 |
| | Whey Protein Concentrate | 7.01 |
| Lipids | High Oleic Sunflower Oil | 23.7 |
| | Canola Oil | 13.4 |
| | Corn Oil | 8.68 |

TABLE 12-continued

| Category | Ingredients | Amount (Kg) |
|---|---|---|
| Emulsifier | Lecithin | 1.45 |
| Minerals | Tricalcium Phosphate | NAP |
| | Magnesium Chloride | 3.4 |
| | Sodium Chloride | 0.26 |
| | Sodium Citrate | 3.8 |
| | Potassium Citrate | 4.34 |
| | Trace/Ultratrace Minerals Premix | 0.25 |
| | Potassium Iodide | 0.0002 |
| Vitamins | Oil Soluble Vitamins Premix | 0.1 |
| | Beta Carotene | 0.01 |
| | Ascorbic Acid | 0.45 |
| | Water Soluble Vitamins Premix | 0.1 |
| Conditional Nutrient Stabilizers | Choline Chloride | 0.6 |
| | Pectin | 8 |
| | Slendid 200 (pectin) | 1.5 |
| | Avicel CL-611 | 3 |
| Antioxidants | Mixed Tocopherols | 0.0009 |
| | Ascorbyl palmitate | 0.0544 |
| Processing Aids | Citric Acid | 5.4 |
| | Phosphoric Acid (85%) | 2.32 |

## EXAMPLE XI

### Production of an Adult Beverage

In

this experiment, a 1000 kg batch of an adult beverage having a caloric density of 1.5 kcal. is prepared using the procedure of Example IV. The product had the following composition. The calcium is provided by the protein sources. A single serving will provide at least 25% of the RDI for calcium (per US standard).

TABLE 13

| Category | Ingredients | Amount (Kg) |
|---|---|---|
| Carbohydrates | Sucrose | 97.4 |
| | Liquid Corn Syrup | 81.1 |
| Proteins | Milk Protein Isolate or Yogurt | 41.8 |
| | Cultured Milk Protein Isolate | |
| | Calcium Caseinate | 11 |
| | Whey Protein Concentrate | 7.61 |
| | Hydrolyzed Fish Gelatin | 6.5 |
| Lipids | High Oleic Sunflower Oil | 23.7 |
| | Canola Oil | 11.4 |
| | Corn Oil | 8.68 |
| Emulsifier | Lecithin | 1.45 |
| Minerals | Magnesium Chloride | 3.44 |
| | Sodium Chloride | 0.25 |
| | Sodium Citrate | 3.85 |
| | Potassium Citrate | 4.39 |
| | Trace/Ultratrace Minerals Premix | 0.25 |
| | Potassium Iodide | 0.0002 |
| Vitamins | Oil Soluble Vitamins Premix | 0.1 |
| | Beta Carotene | 0.01 |
| | Ascorbic Acid | 0.45 |
| | Water Soluble Vitamins Premix | 0.1 |

TABLE 13-continued

| Category | Ingredients | Amount (Kg) |
|---|---|---|
| Conditional Nutrient | Choline Chloride | 0.6 |
| Stabilizers | Pectin | 8 |
| | Slendid 200 (pectin) | 1.5 |
| | Avicel CL-611 | 1 |
| Antioxidants | Mixed Tocopherols | 0.0009 |
| | Ascobyl palmitate | 0.0544 |
| Processing Aids | Citric Acid | 5.4 |
| | Phosphoric Acid (85%) | 2.32 |

## EXAMPLE XII

Production of an Adult Beverage

In this experiment, a 454 kilogram batch of an adult beverage is prepared using the procedure in Example IV.

TABLE 14

| Ingredient | Amount (in Kilograms) |
|---|---|
| Ingredient Water | 392.85 |
| Sucrose | 20.62 |
| Milk Protein Isolate | 6.86 |
| Calcium Caseinate | 4.6 |
| Maltodextrin | 7.25 |
| JMJ Pectin | 3.6 |
| Slendid Type-200 Pectin | 1.8 |
| Potassium Citrate | 1.79 |
| Magnesium Gluconate | 1.38 |
| High Oleic Safflower Oil | 1.37 |
| Calcium Citrate | 1.32 |
| Calcium Glycerophosphate | 1.26 |
| Sodium Citrate | 1.11 |
| Cellulose Gel | 0.9 |
| Magnesium Chloride | 0.62 |
| Ascorbic Acid | 0.17 |
| UTM/TM Premix | 0.16 |
| Canola Oil | 0.16 |

TABLE 14-continued

| Ingredient | Amount (in Kilograms) |
|---|---|
| Lecithin-Centrol CA | 0.05 |
| Vitamins $D_3$, E and $K_1$ Concentrate | 0.04 |
| Vitamin E (d, l- alpha-Tocopheryl Acetate) | 0.02 |
| Sodium Borate | 0.01 |
| Vitamin A Palmitate | 0.0036 |
| Pyridoxine Hydrochloride | 0.002 |
| Ascorbyl Palmitate | 0.002 |
| Folic Acid | 0.007 |
| Tenox GT-2 | 0.0003 |
| Cyanocobalamin | 0.00008 |
| Potassium Benzoate | 0.27 |
| Potassium Sorbate * | 0.135 |

## EXAMPLE XIII

Comparative Example

This Example summarizes experiments that were carried out with an alternative calcium source, calcium citrate malate. Calcium citrate malate is used widely as a calcium source. It is available in a tablet form as a calcium supplement. It also has a history of being incorporated into acidic beverages. It is currently incorporated into Tropicana brands of orange juice. It was expected that calcium citrate malate would work in the beverages of this invention due to their acidic nature. This was not the case. As the data below demonstrates, the calcium citrate malate interacted with the protein resulting in gelling of the beverages.

Beverages having a composition comparable to that in Example XII were prepared. They were manufactured using procedures comparable to those of Example IV. The products were formulated to provide 50% of the USRDI for calcium in an 8 oz serving (0.2 wt. % elemental calcium). As noted below, a few beverages were prepared with only 25% of the RDI.

The calcium citrate malate (CCM) was prepared in the following manner. It was prepared by admixing calcium hydroxide (0.188 wt. %), citric acid (0.122%), and malic acid (0.212%) in water at room temperature. The CCM was then added to the beverage as described in Example IV prior to-acidification or after acidification as noted below. A control beverage having as a calcium source a 60:40 admixture of calcium glycerophosphate and calcium citrate. The following results were obtained:

TABLE 15

| Batch Code | Calcium Source | Ca Addition | Ca % RDI | Sucrose: Complex CHO | Viscosity 1 Week | Protein Stability (Grain) | Sour | Gel |
|---|---|---|---|---|---|---|---|---|
| 1,005 | CaGlyCaCitr | Prior to | 50 | 65:35 | 16.4 | 4 | 1–1½ | — |
| 1,003 | CCM | Acid | 50 | 65:35 | 838 | 6 | 2 | 6 |
| 1,004 | CCM | After Acid | 50 | 65:35 | 88.6 | 6 | 2½ | 6 |

After the failures above, various experiments were conducted to try to add CCM to the formula. They included: order of addition, changes in carbohydrate and acid systems, protein level, stabilizer level and homogenization pressure. Products were evaluated for sensory characteristics and for physical stability with special attention to protein stability and viscosity.

The following results were obtained:

TABLE 16

Evaluation of - Acid and Carbohydrate Systems

| Batch Code | Calcium Source | Acid System | Ca % RDI | Sucrose:Complex CHO | Viscosity 1 Week | Protein Stability (Grain) | Sour | Gel |
|---|---|---|---|---|---|---|---|---|
| 2,001 | CaGly/CaCitrate | Citric/H3PO4 | 50 | 65:35 | 9.5 | 4 | 1½ | — |
| 2,003 | CCM | Citric/Malic | 50 | 65:35 | — | — | 2 | 3 Months |
| 2,004 | CCM | Citric/Malic/ H3PO4 | 50 | 65:35 | — | — | 1½–2 | 3 Months |
| 2,005 | CaGly/CaCitrate | Citric/H3PO4 | 50 | 100:0 | — | — | 1½ | — |
| 2,006 | CCM | Citric/Malic | 50 | 100:0 | — | — | 2–2½ | 3 Months |
| 2,007 | CCM | Citric/Malic | 25 | 100:0 | — | — | 1½ | 3 Months Soft Gel |
| 2,101 | CaGly/CaCitrate | Citric/H3PO4 | 50 | 65:35 | 11 | 4 | 2 | — |
| 2,102 | CCM | Citric/Malic/ H3PO4 | 50 | 65:35 | 46 | 4 | 2 | 6 Months |
| 2,103 | CCM | Citric/Malic/ H3PO4 | 25 | 65:35 | 50.3 | 4 | 2 | 6 Months |
| 2,104 | CaGly/CaCitrate | Citric/H3PO4 | 50 | 80:20 | 11 | 4 | 1 | 6 |
| 2,105 | CaGly/CaCitrate 50% and CCM | Citric/Malic/ H3PO4 | 50 | 65:35 | 37.8 | 4 | 1½ | 6 Months |
| 2,106 | CCM | Citric/Malic/ H3PO4 | 50 | 80:20 | 43 | 4 | 1 | 6 Months |

TABLE 17

Evaluation of - Protein Level

| Batch Code | Calcium Source | Protein Level % | Ca % RDI | Sucrose: Complex CHO | Viscosity 1 Week | Protein Stability (Grain) | Sour | Gel |
|---|---|---|---|---|---|---|---|---|
| 2,201 | CaGly/ CaCitrate | 3.71 | 50 | 80:20 | 9.5 | 4 | 1½ | — |
| 2,202 | CCM | 3.71 | 50 | | — | — | 2 | 3 Months |
| 2,203 | CCM | 2.5 | 50 | | — | — | 1½–2 | 3 Months |
| 2,204 | CCM | 2 | 50 | | — | — | 1½ | — |
| 2,205 | CCM | 1.5 | 50 | | — | — | 2–2½ | 3 Months |
| 2,206 | CCM | 3 | 50 | | — | — | 1½ | 3 Months |

TABLE 18

Evaluation of - Homogenization

| Batch Code | Calcium Source | Homo-genization | Ca % RDI | Sucrose: Complex CHO | Viscosity 1 Week | Protein Stability (Grain) | Sour | Gel |
|---|---|---|---|---|---|---|---|---|
| 3,801 | CaGly/ CaCitrate | single | 50 | 75:25 | 40 | 4 | 3 | — |
| 3,802 | CaGly/ CaCitrate | double | 50 | | 60.8 | 5 | 1½ | — |
| 3,803 | CCM | single | 50 | | 63 | 5 | 2 | 3 Months |
| 3,804 | CaGly/ CaCitrate | single | 50 | | 26.7 | 6 | 2½ | — |
| 3,805 | CCM | single | 50 | | 36.3 | 6 | 2 | 3 Months |

TABLE 19

| | | Evaluation of - Stabilizer | | | | | |
|---|---|---|---|---|---|---|---|
| Batch Calcium Code Source | Stabilizer % | Ca % RDI | Sucrose: Complex CHO | Viscosity 1 Week | Protein Stability (Grain) | Sour | Gel |
| 3,701 CaGly/ CaCitrate | 0.8 | 50 | 75:25 | 54.3 | 5 | 1½ | — |
| 3702 CCM | | | | 381 | 5 | 1½ | 3 months |
| 3,703 CaGly/ CaCitrate | 1 | | | 65.5 | 6 | 1½ | — |
| 3,704 CCM | | | | 119.4 | 6 | 1½ | 3 months |

## Discussion

The addition of CCM before or after acidification was evaluated and results are presented in Table 15 Addition of CCM before acidification was easier and the final product was less sour and less chalky. Sour and chalky mouthfeel were higher in the CCM samples than in the control. In addition, the CCM variables had a higher grain, higher viscosity and gelled after 3 to 6 months of shelf life. The control calcium system is not as soluble as CCM at the product pH of 4.0 to 4.35. It appears that the more soluble calcium from CCM binds with the protein in the formula causing conformational changes and reduced charge. The reduced protein charge permits protein aggregation and gel formation. The initial high grain and viscosity values and the chalky mouthfeel were early indications of protein instability. After few months gelling occurred.

A second set of experiments was designed to try to reduce the sour note in the CCM variables. This was done by increasing the amount of sucrose in the products and by using, in addition to citric and malic acids required in the CCM preparation, phosphoric acid. Results are presented in Table 16. In general, it appears that the use of phosphoric acid reduced the sour note. Since phosphoric acid is a strong acid and it is not very sour, the final product is perceived as less sour. The higher level of sucrose also helped with the sour. All samples with CCM, were chalkier than the control and had higher viscosity. They gelled after 3 to 6 months of storage. A couple of samples were made to deliver 25% RDI for calcium (batch 2007, batch 2103). These samples also gelled, but the gel was described as soft and weak. In addition, one batch was made with a combination of the control calcium salts and CCM (batch 2105). It also gelled in time.

Since the gelling was probably caused by the protein and calcium interaction, the next set of experiments was designed to determine the effect of protein level on gelling. Samples were prepared containing protein ranging from 1.5 to 3.71%. Results presented in Table 19 indicate that in all cases, the samples containing CCM gelled while the control remained unchanged. In most cases, the chalky mouthfeel decreased as the protein content decreased.

Other experiments described in Tables 17 and 18 also demonstrated that CCM caused gelling in the formula.

## Industrial Applicability

Some individuals in need of nutritional supplementation simply do not like or cannot tolerate milky supplements. These individuals may also suffer from taste fatigue which can hinder compliance. This invention will offer individuals a new variety of supplements that will improve intake and thereby improve nutritional status. This invention is primarily directed to a low pH beverage that contains high levels of protein and nutrients which is stabilized through the use of HM pectin alone, or in combination with other stabilizers such as CMC and MCC.

In accordance with the foregoing disclosure, it will be within the ability of one skilled in the relevant arts to make modifications to the present invention, such as through the substitution of equivalent materials and/or their amounts, without departing from the spirit of the invention as reflected in the appended claims.

We claim:

1. A shelf stable liquid enteral formula having a pH of from about 3.0–4.6 comprising:

(a) from about 45–95% by weight water;

(b) from about 1.0–15% by weight of caseinate

(c) from 0.5–3.3% by weight of high methoxy pectin;

(d) from about 1–30% by weight of a carbohydrate;

(e) from about 0.5–10% by weight of an edible oil;

(f) sufficient quantities of protein, carbohydrate, and edible oil to serve as a sole source of nutrition, in a volume ranging from 1000–2000 ml,

(g) at least 100% of the adult RDI for vitamins and minerals, in a volume ranging from 1000–2000 ml, and;

(h) and said enteral formula has a shelf life of at least one year.

2. The enteral formula according to claim 1 in which said edible oil is selected from the group consisting of soy oil, marine oil, canola oil, high oleic safflower oil, high oleic sunflower oil, fractionated coconut oil, olive oil, borage, black currant seed oil, corn, fungal oils, safflower, sunflower, evening primrose, cottonseed, rice bran, grape seed, flaxseed, garlic, peanuts, almonds, walnuts, wheat germ, egg, and sesame.

3. The enteral formula according to claim 1 in which said carbohydrate is selected from the group consisting of dextrose, lactose, fructose, sucrose, maltose, corn starch, hydrolysed corn starch, maltodextrin, glucose polymers, corn syrup solids, oligosaccharides, high saccharides, high fructose corn syrup, and fructooligosaccharides.

4. The enteral formula according to claim 1 wherein said pH is from about 4.0 to about 4.35.

5. The enteral formula according to claim 1 wherein said edible oil is present at a concentration of from about 4.0–6.0% by weight.

6. The enteral formula according to claim 1 wherein said edible oil is selected from the group consisting of high oleic safflower oil, canola oil, soy oil and fractionated coconut oil.

7. The enteral formula according to claim 1 which contains from about 0.1–10% by weight of an acid system comprising at least one food grade acid selected from the group comprising citric acid, phosphoric acid, tartaric acid, lactic acid, malic acid, glucono delta lactone and mixtures thereof.

8. The enteral formula according to claim 1 in which said caseinate is selected from the group consisting of calcium caseinate and sodium caseinate.

9. The enteral formula according to claim 1 in which said caseinate is provided by milk protein isolate.

* * * * *

# EXHIBIT D

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|---|---|---|---|
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| PURAC FCC 50<br>*L(+)-lactic acid edible*<br>*50% solution* | ● | ● | |
| PURAC FCC 80<br>*L(+)-lactic acid edible*<br>*80% solution* | ● | ● | |
| PURAC FCC 88<br>*L(+)-lactic acid edible*<br>*88% solution* | ● | ● | |
| PURAC HS 50<br>*L(+)-lactic acid heat stable*<br>*50% solution* | ● | ● | |
| PURAC HS 88<br>*L(+)-lactic acid heat stable*<br>*88% solution* | ● | ● | |
| PURAC PF 90<br>*L(+)-lactic acid pharmaceutical*<br>*90% solution* | ● | ● | |
| PURAC PH 90<br>*L(+)-lactic acid pharmaceutical*<br>*90% solution* | ● | ● | |
| PURAC Powder H 60<br>*Lactic acid powder* | ● | ● | |

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The lactate esters are available in various qualities including CRG, etc.

| | | |
|---|---|---|
| PURASOLV BL<br>*Butyl lactate* | ● | ● |
| PURASOLV EHL<br>*2-Ethylhexyl lactate* | ● | ● |
| PURASOLV EL<br>*Ethyl lactate* | ● | ● |
| PURASOLV IPL<br>*Isopropyl lactate* | ● | ● |
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*n-Propyl-lactate*

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PURAMEX FE
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- USP: pharmaceutical grade, complies with all major pharmacopoeia
- CRG: chiral reagent grade
- HiPure: optimized odor and/or taste profile
- HS: heat stable
- HQ: high quality
- PH/PF: pharmaceutical pyrogen free


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# EXHIBIT E

**The Use of Lactic Acid Milk in Infant Feeding**

A. B. Schwartz

*The American Journal of Nursing*, Vol. 26, No. 12. (Dec., 1926), pp. 927-932.

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training, of a solidly practical sort, so that there will be a bigger supply of competent candidates; and, second, make the position of superintendent of nurses sufficiently dignified, and with sufficient pay and authority, so that when the hospital gets a good woman, it can keep her.

In conclusion, let me sum up this discussion by telling you what the typical nursing school is like:

**The Typical Nursing School**

It is in the North Central states.

It requires one year of high school for entrance.

It has 28 students.

It is attached to a hospital.

The hospital has a daily average of 65 patients.

Students work a 56-hour week.

The school employs one full-time teacher.

Its present superintendent has been on the job for two years and has just presented her resignation.

# The Use of Lactic Acid Milk in Infant Feeding

By A. B. Schwartz, M.D.

*Attending Physician, Milwaukee Children's Hospital*

INFANTS thrive best on breast milk. Its use has the support of an experience based upon instinct, tradition and scientific fact. Sometimes, due to constitutional causes in the mother, or to social factors (women who must earn their own livelihood, etc.), artificial feeding has to be instituted. In such cases, simple dilutions of cow's milk plus additional carbohydrates will often be the method of choice. Such modifications of milk for an infant should always contain a sufficient number of calories and a proper proportion of fat, protein and carbohydrate, and also be supplemented by vitamins necessary for proper growth and development.

It is the experience of every pediatrist that there are cases of nutritional disturbances in which the simple dilution of cow's milk is not entirely adequate. Particularly is this the case in infants below the normal weight for their age. Such infants demand a food of high concentration which is at the same time easily digestible.

Lactic acid milk affords such a combination. Besides these two considerations, it has other merits making it a valuable adjunct in the artificial feeding problems of infancy. First, its acidity promotes gastric digestion by counteracting the neutralizing effect of the so-called "buffer" substances in cow's milk. These buffer substances in non-acidified cow's milk use up the normal acids of the stomach and thereby hinder digestion. Second, it allows the use of undiluted cow's milk and therefore makes frequent food changes unnecessary. Third, it is equally well digested at all ages of infancy. Fourth, the clinical results reported from its use have been good. Fifth, it is economical. Sixth, it is easily prepared.

The present study comprises the observations of the use of lactic acid milk with varying proportions of carbohydrates in several particular groups of feeding problems seen in hospital practice.

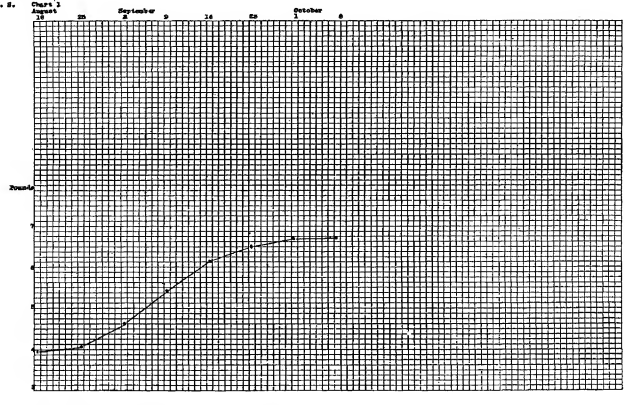
### Group I. Premature Infants

PREMATURE infants are always difficult to raise. For practical purposes, every infant weighing less than 5 pounds must be regarded as a premature infant, regardless of whether it is a 7-months or an 8-months parturition. An infant so tiny can take but small quantities of food at a time. Obviously such food must be of high caloric value in order to produce gain in weight.

Breast milk is without question the ideal food for these babies. It is, however, unfortunate that the very situations that provoke prematurity often make it impossible for normal breast milk feeding. Severe constitutional diseases, such as cardio-renal disease, or tuberculosis, in the mother may contraindicate breast feeding. Certain social factors often militate against the possibility of successful breast feeding. This is often the case in the types of premature infants that are seen in hospital work—the "front doorstep" waif, whose arrival into existence is usually carried in the "green sheet" of the newspaper instead of the birth-notice column.

I present three examples of premature infants fed successfully on lactic acid milk. They illustrate one of its greatest indications. Given proper nursing care, its aim the maintenance of body temperature and the prevention of cross infection, I have seen better results with lactic acid milk than with any other substitute for breast milk.

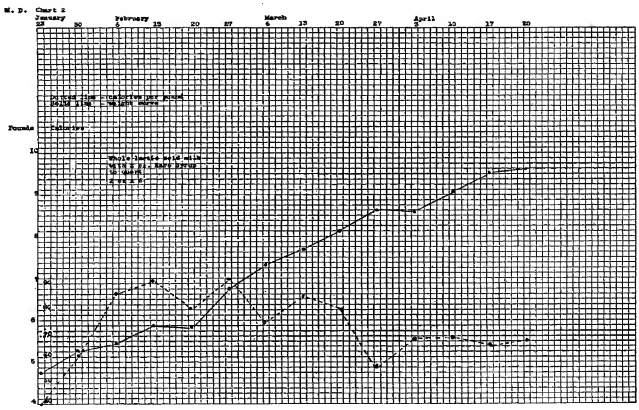
Case 1. (See Chart 1.) W. S., 7 months' birth, born August 4, 1925, and admitted to the Milwaukee Infants' Hospital ten days later, weighing 3½ pounds. Its admission temperature was 96°. The infant was given a ½ dilution of lactic acid milk with 1 ounce of Karo Syrup in 24 hours, 1½ ounces at a feeding, 12 feedings. Ten days later it was




given whole lactic acid milk, undiluted, with 1½ ounces Karo Syrup, two-ounce feedings, 8 feedings. The baby remained at the hospital for 2 months. It was discharged weighing 6¾ pounds. This baby made its best gain receiving 100 to 125 calories per pound.

Case 2. (See Chart 2.) M. D., a 7½ months' birth, born December 31, 1924, was admitted to the Milwaukee Infants' Hospital January 23, 1925, weighing 4 pounds 11 ounces. Admission temperature 97.2°. The infant was put on a formula of whole lactic acid milk with 2 ounces Karo Syrup to the quart. It was fed every 4 hours, two-ounce feedings. It was discharged April 20, 3 months later, weighing 9½ pounds.

Discussion: The first feedings were




given every 4 hours, which is too infrequent for a premature, as it does not allow sufficient food intake in the 24 hours. The infant's best gain was made on a food intake of close to 100 calories per pound. As the baby's weight approached the expected weight of a normal baby, its actual caloric intake was diminished.

Case 3. M. S., 6 months prematurity, born January 2, 1925, and admitted to the Milwaukee Infants' Hospital when 8 days old, weighing 3 pounds, 4 ounces. Temperature would not register on admission. One hour later it was 95.8°. The infant was given breast milk for 3 weeks, then put on whole lactic acid milk with 5 per cent Karo Syrup, later 6 per cent Karo Syrup. It was discharged 3 months later, weighing 7 pounds.

Talbot's experiments on the basal metabolism of prematurity showed that premature infants need an excess of food on account of the relatively greater amount of growth essential for the normal development of these babies. His infants did not gain in weight until they were able to digest approximately 200 calories in the day.

### Group II. Malnutrition

A COMMON group of difficult feeding problems seen by the pediatrist, particularly in his hospital service, are those infants who have been taken off the breast because the baby was not gaining, or was crying too much. Either one of these conditions could probably have been remedied by complementing the breast feeding with a simple milk mixture. In dispensary practice, particularly, one is struck with the frequency with which babies are unnecessarily weaned. Often such babies are tried on inadequate milk mixture so long that dyspepsia develops, and a true food intolerance results.

As Mariott has pointed out, the malnourished infant must receive not only more total calories per pound, but also

more of the necessary elements, such as proteins and mineral salts in order to insure normal growth. In the face of a diminished digestive capacity, these infants must receive a concentrated food easily digested. The usual milk mixtures do not fulfill these two requirements, but acidified milk, enriched with an assimilable carbohydrate, furnishes such a combination.

The following cases represent examples of this type of food disturbance which were treated by the use of lactic acid milk with varying amounts of sugar.

Case 4. (See Chart 4.) L. J., born October 10, 1924, weighing 7¼ pounds. Was nursed for 3 weeks, then put on whole milk. Admitted to the Milwaukee Infants' Hospital, January 16, 1925. Age 3 months; weight 6 pounds, 3 ounces. The baby was given whole lactic acid milk with 3 per cent Karo Syrup, and slowly increased to 10 per cent Karo Syrup, 7 feedings in 24 hours, 4 to 5 ounces at a feeding. Discharged February 26, 1925, after a 6 weeks' stay, weighing 9 pounds, 14 ounces. Chart 4, interrupted line indicates the intake of calories per pound. At one point, this infant was receiving 120 calories per pound, 2½ times the caloric needs of a normal infant.

Case 5. F. S., born January 5, 1925, weighing 8 pounds, 7 ounces. Admitted to Milwaukee Infants' Hospital on January 28, 1926, age 2 weeks, weight 7 pounds. Was breast fed for 2 weeks and was then getting milk and water. The baby was put on whole lactic with 5 per cent Karo Syrup which was later increased to 6, 7, 8 and 10 per cent. On discharge, the Karo Syrup was reduced to 5 per cent. Discharged March 31, 1925, after a 2 months' stay, weighing 12 pounds.

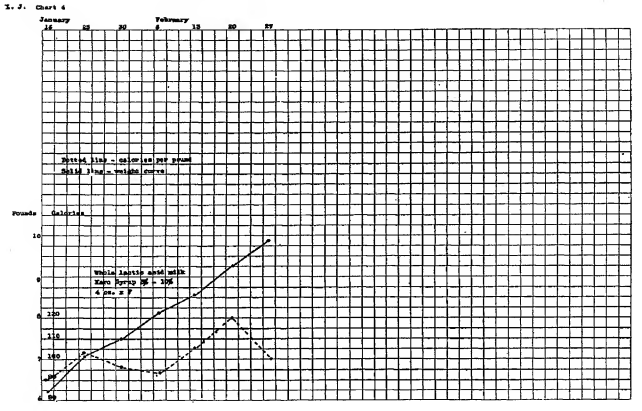
**Group III. Parenteral Food Disturbances**

A STUDY of the severe digestive disturbances seen in infants in hospitals as well as observations of these upsets witnessed in one's private practice drives one more and more to the conclusion that the majority of these upsets are the result of throat infections —so called parenteral infections. A better understanding of this relationship would reduce the number of difficult feeding cases by obviating the frequent changes of formulas which are said "to disagree." Very often, infants who have been subjected to the constantly varying proportions of milk dilutions are brought to the hospital with symptoms of a food disturbance superimposed on an infectious process. The following cases illustrate this type of food disturbance.

Case 6. J. M. First seen at 3 months of age with a diarrhea following a nose and throat infection. Had been fed first on Imperial Granum, then on condensed milk. Birth weight 9 pounds (?) Weight on first examination 9 pounds, 3 ounces. The infant was given whole lactic acid milk with 5 per cent Karo Corn Syrup, after a 4 days' period of skimmed lactic acid milk with 4 per cent Karo Syrup. Hospital stay 2 weeks. Weight on discharge 10 pounds.

At 10 months of age, this same infant was again seen with a similar parenteral digestive upset, slight fever, loose bowels and weight loss. On account of the infant being an extremely nervous hypertonic infant, she was sent to the hospital for treatment. She was put on skimmed lactic acid milk with 3 per cent Karo Syrup for 5 days, on ½ skimmed lactic and ½ whole lactic for 2 days, then on whole lactic acid milk. In 9 days, the baby gained 1½ pounds, and by that time was well enough to be put on a mixed diet, when she made a very rapid weight gain. Discharged after a 3 weeks' stay, with a weight gain of 3½ pounds.

Case 7. R. R., born October 23, 1924, weight 8½ pounds, was first seen when 4 months of age, weighing 8 pounds, 15 ounces. Was never breast-fed. Had milk and water with Dextri Maltose, Malted milk, Imperial Granum, condensed milk and egg white in water for varying periods of time. The infant had gone through several attacks of high fever associated with digestive upsets, and at 4 months, when admitted to the Milwaukee Infants' Hospital was very undernourished, had bronchitis and a swelling of one knee which was diagnosed as a toxic arthritis. The Von Pirquet test, Mantoux test, Roentgenograph of chest, were negative. Roentgenograph of the knee showed no changes. The leg was put in extension. The food was changed to fat free lactic acid milk with 3 per cent Karo Syrup. The baby remained at the hospital for one month, gained 2 pounds, and was then put on whole lactic




acid milk, and made a rapid and uneventful recovery.

Case 8. J. C., age 3½ months, had been sick a week with sore throat and digestive upset—diarrhea and vomiting. He was given water only, for 3 days, green tea for 2 days, and for the 2 days preceding admission to the hospital had been allowed a 1-3 milk mixture. Admitted to the Milwaukee Infants' Hospital with loose stools, weighing 12 pounds, 12 ounces. He was put on whole lactic acid milk with 3 per cent Karo Syrup, which feedings he took very eagerly. Gained 10 ounces in 10 days. Discharged while on formula of 36 ounces whole lactic acid milk with 4 per cent Karo Syrup, 6 feedings, 4 ounces each.

During the past three years, I have used lactic acid milk almost routinely in my medical service at the Milwaukee Children's Hospital and at the Milwaukee Infants' Hospital, as well as in selected cases in private practice. Some of these infants received cultured lactic acid milk, others, lactic acid milk prepared with commercial lactic acid. Commercial lactic acid has given equally good results. This is prepared according to Marriott's instructions, only the amount of acid is varied according to the particular case. The usual prescription is as follows:

Boil one quart of certified milk for five minutes. Cool. When thoroughly cooled, add 124 drops lactic acid (ask druggist for United States Pharmacopeia Lactic Acid). Add the lactic acid drop by drop, stirring after the addition of each drop. Use an ordinary medicine dropper. Add 2 ounces Karo Corn Syrup. Mix thoroughly into the milk mixture.

The most common objection to the use of lactic acid milk has been the aesthetic objection raised by parents to feeding "sour milk" to a baby. This is obviously an irrelevant objection. The other objections occasionally heard are that the food is not willingly taken and that the food is regurgitated. The first objection is more often encountered in private practice than in hospital work. It is usually overcome after a few days by patiently persisting in its use. It is

equally worth noting that infants who have been on lactic acid milk for a long time refuse sweet milk when it is first offered. The second objection, regurgitation of the food, may be overcome by reducing the amount of the subsequent feedings.

Infants who have once been put on whole lactic acid milk with the proper proportion of carbohydrates need only the necessary food additions of cereal, vegetables, orange juice and cod-liver oil in their subsequent management. The usually frequent changes of the formula itself are obviated—a very worth while simplification of infant feeding.

Equally good results have been obtained with other forms of acidified milk, such as the hydrochloric acid milk advised by Faber, or Hess's orange-juice milk.

Summary: In premature infants, for whom breast milk cannot be obtained, in malnutrition and in parenteral digestive disturbances, lactic acid milk provides a food mixture which is easily digested, possessing a high caloric value. It is easily prepared and obviates the needs of frequent food changes. Its routine use in cases of these types has given excellent results. It is a valuable adjunct in the management of certain nutritional problems frequently seen in infants.

# The Relation of Nursing Care to Postoperative Pneumonia

By Carolyn Henneberger, R.N.

NO patient is ever operated on in the Joseph Price Hospital who has a cold or who is just getting over one and great care is taken that the patient is not chilled before operation. In the course of twenty years in the hospital we have had only two cases of postoperative pneumonia, one of whom was a patient who had been addicted to the use of alcohol. This, we feel justified in saying, is due largely to the good nursing care the patient receives.

Just before leaving the operating room, a large old-fashioned mustard plaster is placed on the patient's chest and is left there until the skin becomes reddened. A large piece of flannel is then placed on the chest and is left there all day.

After coming from the operating room, the patient is carefully watched and when the operation has been a major one, the patient is not left alone for twenty hours. With such close observation, any change for the worse is seen at once and reported, which saves many a life.

All of our patients who have had an abdominal section without pus, have their beds elevated as soon as they come from the operating room. We believe this action to be a great preventive of shock.

We keep water away from all our patients who have undergone a major operation for twenty hours. At this time small sips of hot water are given, provided there is no nausea or vomiting. This is followed by cold water, in small amounts at first until we are sure there is no danger of disturbing the patient's stomach. We do not believe in giving a surgical patient anything by mouth as long as there is any danger of nausea or vomiting.

# EXHIBIT F

**Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents**

**WHO FOOD ADDITIVES SERIES NO. 5**

The evaluations contained in this publication were prepared by the Joint FAO/WHO Expert Committee on Food Additives which met in Geneva, 25 June - 4 July 1973[1]

World Health Organization
Geneva
1974

[1] Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.

## LACTIC ACID AND ITS AMMONIUM, CALCIUM, POTASSIUM AND SODIUM SALTS

### Explanation

These compounds have been evaluated for acceptable daily intake by the Joint FAO/WHO Expert Committee on Food Additives (see Annex 1, Ref. No. 13) in 1966.

Since the previous evaluation, additional data have become available and are summarized and discussed in the following monograph. The previously published monograph has been revised and is reproduced in its entirety below.

### BIOLOGICAL DATA

### BIOCHEMICAL ASPECTS

L(+)-lactate is a normal intermediary of mammalian metabolism. It arises from glycogen breakdown, from amino acids and from dicarboxylic acids, e.g. succinate. Some micro-organisms specifically produce lactic acid as major product of the metabolism; L. delbrueckii produces L(+)-lactic acid, the physiological isomer, and

L. leichmanii, the D(-)-isomer.

Various groups of rats were killed three hours after the administration of L(+), D(-) or DL-lactic acid (1700 mg/kg) orally or by s.c. injection. The L(+)-isomer produced the largest rise in liver glycogen; 40-95% of the L(+)-lactate absorbed in three hours being converted; practically none was formed from the D(-)-isomer. D(-)-lactate produced the highest blood lactate level and 30% of the amount absorbed was excreted in the urine; no L(+)-lactate was found. D(-)-lactate was utilized four times more slowly but both D(-) and L(+)-isomers were absorbed at the same rate from the intestine (Cori & Cori, 1929). The absorption of sodium DL-lactate from the intestine of groups of six male and female rats was determined at one, two, three and four hours after oral feeding of 215 mg/kw bw of material. The rate of absorption decreased with time and was roughly proportional to the amount of lactate present in the gut. Slow evacuation of the stomach limited the rate of absorption in some animals (Cori, 1930). At blood levels over 200 to 250 mg lactate, rabbits showed excitation, dyspnoea and tachycardia (Collazo et al., 1933).

After oral administration to a human subject of 1 to 3000 mg lactate, 20 to 30% was excreted in the urine during 14 hours (Fürth & Engel, 1930).

When sodium DL-lactate was given i.v. to starving dogs, 7 to 40% was recovered in the urine, none was found in the faeces (Abramson & Eggleton, 1927). Rabbits were given orally 600 to 1600 mg/kg bw of racemic lactic acid. Most animals died within three days. Urinary excretion varied between 0.26 and 31%. Alkalosis did not affect the excretion (Fürth & Engel, 1930).

In vitro studies have shown that mammalian tissue produces only L(+)-lactate although some tissues can oxidize both isomers. Rat liver tissue used almost entirely L(+) and practically no D(-)-isomer, as measured by oxygen consumption and carbohydrate synthesis. Rat kidney tissue used a definitely measurable amount of D(-)-isomer. Grey matter of rat brain was unable to utilize the D(-)-isomer. L(+)-lactate stimulated oxygen consumption and $CO_2$ production of all rat tissues; similarly D(-)-lactate slightly stimulated respiration of liver and heart but not brain tissue. Similar effects occurred in duck tissue. Heart tissue is able to utilize both isomers almost equally well. $^{14}C$-L(+)-lactate produces $^{14}CO_2$ more rapidly than D(-)-lactate in the intact rat although the D(-) form is fairly well metabolized. After two hours, both isomers are oxidized at equal rates (Brin, 1964). More recent studies have defined the cell sites for metabolizing the isomers in micro-organisms and higher animals and identified the pathways in normal animals, cattle with D(-) lactacidosis and mentally ill patients (Brin, 1964).

L(+)-lactate was oxidized three to five times as rapidly as D(-)-lactate by duck and rat heart and liver slices and 10 to 20 times as rapidly by brain slices, using $^{14}C$ labelled substrate, as shown by oxygen consumption and $^{14}CO_2$ production. The D(-)-isomer was used equally as well as the L(+)-isomer by duck and rat heart slices, two-thirds as well by brain and one-third as well by duck and rat liver and duck brain. High utilization of D(-)-isomer requires special metabolic pathways (Brin et al., 1952).

TOXICOLOGICAL STUDIES

Acute toxicity

| Animal | Route | $LD_{50}$ (mg/kg bw) | References |
|---|---|---|---|
| Rat | i.p. (Sod. lactate) | 2 000 | Rhône-Poulenc, 1965 |
| | oral (lactic acid) | 3 730 | Smyth et al., 1941 |
| Guinea-pig | oral | 1 810 | Smyth et al., 1941 |
| Mouse | oral | 4 875 | Fitzhugh, 1945 |

Rats have been stated to survive 2000 to 4000 mg/kw bw administered s.c. Mice were killed by subcutaneous doses of 2000 to 4000 mg/kg bw whether or not alkalosis was present (Fürth & Engel, 1930). In man, accidental intraduodenal administration of 100 ml 33% lactic acid was fatal within 12 hours (Leschke, 1932). Other workers quote an adult human maximum tolerated dose of 1530 mg/kg bw (Nazario, 1952).

Short-term studies

Rat

Groups of two animals received daily doses of 1000 and 2000 mg/kg bw of sodium lactate (as lactic acid) over 14 to 16 days; Body analyses showed no cumulation (Fürth & Engel, 1930).

Dog

Two dogs received 600 to 1600 mg/kg bw of lactic acid orally 42 times during 2.5 months without ill effects (Faust, 1910).

Bird

Feeding of 10% lactic acid has been blamed for the development of polyneuritic crises resembling $B_1$ deficiency on diets rich in carbohydrates, proteins or fats (Lecoq, 1936).

Long-term studies

No animal studies are available.

OBSERVATIONS IN MAN

Infants

Forty full-term newborn infants were given a commercial feeding formula containing 0.4% DL-lactic acid. No effect was observed on the rate of weight gain, from the second to the fourth week of life (Jacobs & Christian, 1957).

Healthy babies were fed milk formulae acidified with 0.4 to 0.5% DL-lactic acid for periods of 10 days, during the first three months of their life. An increase in the titrable acidity of the urine and

lowering of urinary pH was observed. Babies on "milk rich" formula (4/5 milk mixture) excreted twice as much acid in the urine as babies on diets containing less milk and approximately 33% developed acidosis. Clinical manifestations were: decrease in the rate of body weight gain and decrease in food consumption. On replacing the acidified diet with "sweet milk" diet these effects were reversed very rapidly (Droese & Stolley, 1962).

When 0.35% DL-lactic acid was administered to healthy babies from the tenth to the twentieth day of life, a threefold increase in the urinary excretion of the physiological L(+)-lactic acid and a twelvefold increase in the D(-)-lactic acid was observed. On withdrawing lactic acid from the diet the level of lactic acid excreted in the urine returned to normal. Since the racemic mixture used consisted of 80% of the L(+) and 20% of the D(-) forms it seems that the metabolism of the D(-) form by the young full-term baby is more difficult than the L(+) form. The increase in the urinary excretion of either form of lactic acid indicated that the young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in the diet. A number of babies could not tolerate lactic acid. In such cases there was rapid loss of weight, frequent diarrhoea, reduction of plasma bicarbonate and increased excretion of organic acids in the urine. All these effects were reversed on withdrawing lactic acid from the diet (Droese & Stolley, 1965).

Man has consumed fruits, sour milk and other fermented products containing DL-lactic acid for centuries, apparently without any adverse effects.

Comments:

In evaluating lactic acid, emphasis is placed on its well-established metabolic pathways after normal consumption in man. It is an important intermediate in carbohydrate metabolism. However, human studies determining the maximum load of lactate are not available. There is some evidence that babies in their first three months of life have difficulties in utilizing small amounts of DL and D(-) lactic acids.

EVALUATION

No limit need be set for the acceptable daily intake for man.

Estimate of acceptable daily intake

Not limited*

Neither D(-)-lactic acid nor (DL)-lactic acid should be used in infant foods.

FURTHER WORK OR INFORMATION

Desirable: Metabolic studies on the utilization of D(-) and DL-lactic acid in infants.

* See relevant paragraph.

REFERENCES

Abramson, H. A. & Eggleton, P. (1927) J. Biol. Chem., 75, 745, 753, 763

Brin, M. (1964) J. Ass. Food and Drug. Off., 178

Brin, M., Olson, R. E. & Stare, F. J. (1952) J. Biol. Chem., 199, 467

Collazo, J. A., Puyal, J. & Torres, I. (1933) Anales Soc. Esp. Fis. Quim., 31, 672

Cori, C. F. & Cori, G. T. (1929) J. Biol. Chem., 81, 389

Cori, G. T. (1930) J. Biol. Chem., 87, 13

Droese, W. & Stolley, H. (1962) Dtsch. med. J., 13, 107

Droese, W. & Stolley, H. (1964) Symp. über die Ernäbrung der Frühgeborenen, Bad Schachen, May 1964, 63-72

Faust, E. S. (1910) Cothener Chem. Z., 34, 57

Fitzhugh, O. G. (1945) Unpublished data, submitted to WHO

Fürth, O. & Engel, P. (1930) Biochem. Z., 228, 381

Jacobs, H. M. & Christian, J. R. (1957) Lancet, 77, 157

Lecoq, M. R. (1936) C.R. Acad. Sci., 202, 1304

Leschke, E. (1932) Munch. Med. Wschr., 79, 1481

Nazario, G. (1951) Rev. Inst. Adolfo Lutz, 11, 141

Rhône-Poulenc (1965) Unpublished report

Smyth, H. F. jr, Seaton, J. & Fischer, L. (1941) J. Ind. Hyg. Toxicol., 23, 59

See Also:
Toxicological Abbreviations

# EXHIBIT G

# FUNDAMENTALS OF DAIRY CHEMISTRY

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To
BYRON H. WEBB

for his outstanding dedicated service to the dairy industry that spans half a century and whose persistence and guidance has led to another edition of Fundamentals.

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# Preface

Fundamentals of Dairy Chemistry has always been a reference text which has attempted to provide a complete treatise on the chemistry of milk and the relevant research. The third edition carries on in that format which has proved successful over four previous editions (*Fundamentals of Dairy Science* 1928, 1935 and *Fundamentals of Dairy Chemistry* 1965, 1974). Not only is the material brought up-to-date, indeed several chapters have been completely re-written, but attempts have been made to streamline this edition. In view of the plethora of research related to dairy chemistry, authors were asked to reduce the number of references by eliminating the early, less significant ones. In addition, two chapters have been replaced with subjects which we felt deserved attention: "Nutritive Value of Dairy Foods" and "Chemistry of Processing." Since our society is now more attuned to the quality of the food it consumes and the processes necessary to preserve that quality, the addition of these topics seemed justified. This does not minimize the importance of the information in the deleted chapters, "Vitamins of Milk" and "Frozen Dairy Products." Some of the material in these previous chapters has been incorporated into the new chapters; furthermore, the information in these chapters is available in the second edition, as a reprint from ADSA (Vitamins in Milk and Milk Products, November 1965) or in the many texts on ice cream manufacture.

Originally, *Fundamentals of Dairy Science* (1928) was prepared by members of the Dairy Research Laboratories, USDA. Over the years, the trend has changed. The present edition draws heavily from the expertise of the faculty and staff of universities. Ten of the 14 chapters are written by authors from state universities, three from ARS, USDA, and one from industry.

It seems fitting that this is so. The bulk of future dairy research, if it is to be done, appears destined to be accomplished at our universities. Hopefully the chapter authors have presented appropriate material and in such a way that it serves best the principal users of this book, their students. As universities move away from specific product technology and food technology becomes more sophisticated, a void has

been created where formerly a dairy curriculum existed. It is hoped that this edition of *Fundamentals of Dairy Chemistry* which incorporates a good deal of technology with basic chemistry can help fill this void.

Preparation of this volume took considerably longer than anticipated. The exigencies of other commitments took its toll. Originally the literature was supposed to be covered to 1982 but many of the chapters have more recent references.

I wish to acknowledge with appreciation the contribution made by the chapter authors and the associate editors. Obviously without their assistance, publication of this edition would not have been possible. Dr. Jenness was responsible for Chapters 1, 3, 8, and 9; Dr. Keeney, Chapters 4, 5, and 10; Dr. Marth, Chapters 2, 13, and 14; and Dr. Wong, Chapters 6, 7, 11 and 12.

# EXHIBIT H

# United States Patent [19]

**Takahata**

[11] **4,212,893**

[45] **Jul. 15, 1980**


[54] **ACIDIFIED WHOLE MILK BEVERAGE AND METHOD OF PREPARATION**


[75] Inventor: **Jungo Takahata, Machida, Japan**

[73] Assignee: **Honey Bee Corporation, Tokyo, Japan**



[21] Appl. No.: **910,286**

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[56] **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 2,818,342 | 12/1957 | Ransom | 426/584 |
| 3,432,306 | 3/1969 | Edwards | 426/330.2 |
| 3,647,476 | 3/1972 | Swisher | 426/584 |
| 3,692,532 | 9/1972 | Shenkenberg et al. | 426/584 |
| 4,046,925 | 9/1977 | Igoe | 426/580 X |
| 4,078,092 | 3/1978 | Nishiyama | 426/599 X |

FOREIGN PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 284278 | 4/1929 | United Kingdom | 426/584 |
| 986940 | 3/1965 | United Kingdom | 426/580 |



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[57] **ABSTRACT**


An acidified whole milk beverage having an acidic pH and containing locust bean gum as a stabilizer. An aqueous solution of locust bean gum is added to whole milk after which a fruit juice or organic acid is added thereto to impart the acidic pH. The milk beverage is then homogenized and sterilized.


**13 Claims, No Drawings**

# ACIDIFIED WHOLE MILK BEVERAGE AND METHOD OF PREPARATION

This invention relates to an acidified beverage of whole milk, and more particularly to an acidified beverage of whole milk which maintains a stable emulsified state, wherein curd is not segregated, although the whole milk has not been stripped of fat.

Milk beverage is a kind of soft drink prepared from whole milk or skim milk with addition of, for example, sugar. A flavorful milk beverage wherein the main component, whole milk or skim milk, is mixed with sugar, fruit flavour and coloring matter is known. Such milk beverage is favourably accepted as the type having a peculiar milk flavour but not an acid beverage.

On the other hand, acid beverages having a pH value less than 4.5 is a refreshing beverage of high acidity. As is well known, fruit juice beverage is a typical acid beverage.

At present when a flavorful beverage is increasingly accepted, strong demand is made to provide new milk-containing acid beverage concurrently possessing a flavour peculiar to milk and a refreshing taste derived from high acidity. However, when mixed with acid, fat and protein contained in milk are coagulated and segregated in the form of curd. This tendency is particularly noticeable in whole milk unstripped of fat. Therefore, whole milk has hitherto failed to be used as one component of such acid beverage.

Sour milk beverage is known as a kind of said beverage wherein the main component is skim milk stripped of fat. This is a drink prepared from skim milk fermented by lactic acid bacteria with addition of, for example, sugar. However, this known milk beverage, which is indirectly acidified skim milk by an acid resulting from fermentation by lactic acid bacteria, is distinctly different from the whole milk-containing acidified beverage of this invention which is acidified by direct addition of an acidifying agent.

As described above, acidified beverage containing whole milk has not been known to date. The reason is that when mixed with an acidifying agent such as fruit juice or lactic acid, the whole milk is divided into a liquid portion and a coagulated portion referred to as curd, failing to provide a uniformly emulsified milk beverage.

It is accordingly the object of this invention to provide a whole milk-containing acidified beverage which is maintained in a stable emulsified state due to the use of a special stabilizing agent.

The present inventor has discovered that use of a very small amount of locust bean gum as a stabilizing agent enables whole milk to maintain a stable emulsified state without causing the curd to be segregated from the whole milk even when mixed with fruit juice or organic acid.

According to the invention, there is provided a whole milk-containing acidified beverage which mainly contains whole milk and fruit juice and/or organic acid and further contains locust bean gum as a stabilizing agent, and is thereby maintained in a stable emulsified state. In a preferred embodiment, the whole milk-containing acidified beverage of the invention can retain a more stable emulsified state by using pectin or agar as an auxiliary stabilizing agent together with the locust bean gum used as the main stabilizing agent.

The acidified beverage of this invention mainly contains whole milk. The whole milk may be cow's milk, goat's milk or sheep's milk. Since, however, cow's milk is generally accepted, the following description relates to a cow's milk.

The whole milk used with the acidified beverage of this invention may be a commercially available market milk prepared by treating raw milk for use as beverage. The whole milk contains about 3.3% or over of milk fat in the form of extremely fine fat particles. The pH value of whole milk is generally 6.4 to 6.6. Further, the whole milk containing fat is superior to skim milk in respect of nutrition, calorie and taste.

The fruit juice used with the acidified beverage of the invention may be extracted from any fruit. A fruit puree is included in the scope of the fruit juice. However, preferred are the juices of, for example, oranges, pineapples, apples, grapes, grapefruits, lemons, melons and strawberries. Where lemon juice of high acidity is used, it may be unnecessary to apply any extra organic acid in order to acidify the beverage. Yet, it is generally advised to use both fruit juice and organic acid in order to acidify the beverage in the easily drinkable form and also prevent the beverage from putrefaction. According to the invention, the finished whole milk-containing acidified beverage is so controlled as to have a pH value falling within the range of 2.5 to 4.5, or preferably 3.0 to 4.0, or more preferably 3.4 to 3.6. Or, it is possible to acidify the beverage simply using an organic acid without also using fruit juice.

Any organic acid is applicable, provided its use is acceptable for manufacture of beverage. Organic acids available for the present beverage include, for example, succinic acid, lactic acid, malic acid, tartaric acid, citric acid, gluconic acid and ascorbic acid. Particularly preferred are lactic acid and citric acid.

According to the invention, locust bean gum is used as a stabilizing agent for preventing the fat and protein of the whole milk from being segregated in the form of curd. Commercially available locust bean gum may be used in the form of solids or an aqueous solution. It is preferred to use pectin or agar with locust bean gum. Use of these auxiliary stabilizing agents provides a beverage which is soft and pleasant to the palate due to the fat and protein of the milk being dispersed in a more stable condition.

Obviously, the acidified beverage of whole milk of this invention may be mixed with not only the above-mentioned components but also the customary additives, such as sugar, in order to meet the relish of consumers. Addition of these additives can be easily effected by those skilled in the art and is of course included in the scope of this invention. Additives usable with the present acidified beverage of whole milk include natural sweetening agents such as cane sugar and grape sugar, synthesized sweetening agents, flavouring agents such as orange flavour, seasonings such as aminoacid, colouring matter, table salt and all other auxiliary condiments used in this particular field. Further, any other authorized additives such as an antioxidant may obviously be used. The saccharinity of the present acidified beverage of whole milk varies with the kind of fruit juice added. Generally preferred is the saccharinity of about 10° to 13° as measured by a saccharimeter.

The present acidified beverage of whole milk is prepared through the following steps:

(1) locust bean gum is dissolved in whole milk;

(2) the whole milk emulsion which is formed is mixed at a temperature of 35° to 60° C. with at least one acidifying agent selected from the group consisting of fruit juice and organic acid; and

(3) the acidified whole milk emulsion is homogenized.

In the first step, the locust bean gum may be added in the form of powder, but it is more convenient to apply said gum in the form of an aqueous solution. Part or all of the usable additives can be dissolved in the aqueous solution of locust bean gum. It is preferred to add sweetening agents and table salt to said solution, followed by thermal sterilization. The locust bean gum is readily soluble in water at a higher temperature than about 80° C. The locust bean gum should be added in an amount of 0.1 to 1.0% by weight or preferably 0.2 to 0.3% by weight based on the total weight of the finished product. Addition of the locust bean gum over 1.0% by weight will result in a finished product too viscous for beverage. An auxiliary stabilizing agent such as pectin or agar should be added together with the locust bean gum in an amount smaller than 0.1% by weight, or preferably 0.03 to 0.06% by weight of the finished product. Use of these auxiliary stabilizing agent provides an acidified beverage of whole milk which is more stable and softer to the palate. Agar is preferred in respect of handling.

In the second step, an emulsion of whole milk containing the locust bean gum is mixed with fruit juice, organic acid or a mixture thereof, followed by thorough stirring. The fruit juice or organic acid should be added after the locust bean gum is fully dissolved in whole milk. The reason is that if a whole milk free from locust bean gum is added to fruit juice or organic acid, then fat and casein will be segregated in the form of curd. The temperature at which the emulsion of whole milk is mixed with fruit juice or organic acid in the second step is an important factor. A temperature lower than 35° C. will require a long time to convert the mixture into a stable emulsion. Conversely, a temperature higher than 60° C. will readily give rise to the abovementioned segregation. Therefore, the emulsion of whole milk containing the locust bean gum should be mixed with fruit juice or organic acid at a temperature of 35° C. to 60° C., or preferably 40° C. to 50° C. The mixed whole milk should preferably be stirred about 10 to 30 minutes at said temperature or while the solution is allowed to cool, in order to stabilize the emulsified acidified whole milk.

It is desired that addition of additives or ingredients other than the fruit juice or organic acid be completed, before the second step is brought to an end. The pH value of the acidified beverage of whole milk is controlled, if necessary, during the second step.

According to this invention, whole milk and fruit juice or organic acid may be mixed together in any optional ratio. To assure a pH value of 2.5 to 4.5 required for an acid beverage, however, it is necessary to add a larger amount of fruit juice or organic acid as the amount of whole milk increases. Generally, the proportion of whole milk should preferably fall within the range of about 10 to 60% by weight based on the total weight of the finished product. A smaller content of whole milk provides a more acidified product, whereas a larger proportion of whole milk produces a beverage in which the milk flavour surpasses the acid flavour.

In the third step, the acidified emulsion of whole milk prepared in the second step is homogenized for greater stability. This homogenizing step can be effected under the customary condition using a homogenizer, for example, the Gauline homogenizer generally used in the homogenized milk-producing industry. When said Gauline homogenizer is used, the acidified milk emulsion is forced out of very fine orifices under high pressure. In this case, the rapid pressure drop breaks up fat particles into far smaller form. Therefore, it is possible to produce an acidified beverage of whole milk which can maintain a very stable emulsified condition for a long time, though the pH value is lower than 4.5.

The acidified beverage of whole milk according to this invention can be marketed in a metal or paper container. Before being placed in the container, the acidified milk beverage is sterilized in the same manner as market milk, that is, quickly at high temperature or slowly at low temperature. Preferably, sterilization is carried out for 15 seconds at high temperature, for example, 80° C. When a metal container is used, the acidified beverage of whole milk is quenched to a lower temperature than about 15° C. after being placed into the metal container. When a paper container is used, the beverage is quenched to a lower temperature than about 4° C. before being filled in the paper container.

The acidified beverage of whole milk of this invention is designed to have a pH value of 2.5 to 4.5, or preferably 3.0 to 4.0, or more preferably 3.4 to 3.6. This beverage maintains a stable emulsified condition free from segregated curds of milk fat and protein in spite of the above-mentioned low pH value and the inclusion of whole milk. This advantageous effect is assumed to result from the fact that molecules of locust bean gum coat the fine milk fat solids, thereby preventing their segregation.

The acidified beverage of whole milk according to this invention is characterized by not only a flavour of milk but also a refreshing acid taste. Where acidified by fruit juice, the beverage is provided with the taste, flavour and colour of said fruit juice. The present acidified beverage of whole milk is superior to the prior art acid beverage containing skim milk with respect to nutrition and calorie.

Further, the present acidified beverage of whole milk whose pH value is lower than 4.5 retards the propagation of remaining microbes and consequently has longer shelf life than the conventional similar products.

This invention will be more fully understood by reference to the examples which follow. It will be noted that the conditions such as the composition of an acidified beverage of whole milk and temperature used in the examples will not restrict the invention in any way.

## EXAMPLE 1

5 kg of cane sugar, 1.5 kg of grape sugar, 20 g of table salt and 200 g of locust bean gum were thoroughly dissolved with stirring in 20 l of water at 80° C. The mixture was boiled 20 minutes at 90° C. for sterilization. After cooled, the solution was mixed with 15 l of commercially available whole milk and a proper amount of orange flavour, followed by full stirring. 7.5 l of orange juice and 150 g of citric acid were dissolved in 10 l of warm water. This solution was added to the above-mentioned solution containing the milk and locust bean gum at a temperature of about 50° C. in about 5 minutes, followed by stirring. Later, stirring was continued about 20 minutes at the same temperature. At this time, citric acid was added in a sufficient amount to set the pH value of the entire solution at 3.5. Last, homogenization was carried out by the Gauline homogenizer, pro-

viding an acidified beverage of whole milk maintained in a stable emulsified condition free from segregated curds. The product had a saccharinity of 11° as measured by the Abbe's saccharimeter.

After being sterilized at 80° C., the acidified beverage of whole milk was placed into a metal container, followed by quenching to 15° C. After being stored one year, the beverage did not contain any sediment, but maintained a stable emulsified condition.

## EXAMPLE 2

Acidified beverage of whole milk was produced substantially in the same manner as in Example 1, except that not only 200 g of locust bean gum but also 40 g of agar were jointly used as a stabilizing agent. An acidified beverage of whole milk thus prepared maintained a stable emulsified state free from segregated curds.

## EXAMPLE 3

100 g of cane sugar, and 3 g of locust bean gum were dissolved with stirring in 200 cc of water at 85° C. 400 cc of whole milk was added to the solution. Later, 1 g of citric acid, and 4 cc of lactic acid were added at a temperature of about 50° C. in about 3 minutes. 0.3 cc of lemon flavour was added to the mixture. The whole mass was stirred about 20 minutes at a temperature of about 50° C. Further, citric acid was added in a sufficient amount to set the pH value of the milk beverage thus prepared at 3.5. Finally, the mixed mass was homogenized by the Gauline homogenizer, providing an acidified beverage of whole milk lacking fruit juice. This product also maintained a stable emulsified state free from segregated curds.

What is claimed is:

1. A method of manufacturing a stable, emulsified, acidified whole milk beverage which comprises

(1) adding an aqueous solution of locust bean gum to whole milk, the amount of locust bean gum being 0.3% by weight based on the total weight of said milk beverage, and agitating to form a whole milk emulsion;

(2) mixing said whole milk emulsion with at least one acidifying agent selected from the group consisting of fruit juice and organic acids acceptable for use with a beverage, at a temperature of 35° to 60° C., to form an acidified emulsion having a pH of between 3.4 and 3.6;

(3) stabilizing said acidified emulsion by stirring for 10 to 30 minutes;

(4) homogenizing said stabilized acidified emulsion of whole milk; and then

(5) sterilizing said stabilized, acidified emulsion of whole milk and placing it into a container, thereby producing a stable, emulsified whole milk, free from segregated curds, having a pH of from 3.4 to 3.6.

2. The method according to claim 1, wherein agar or pectin is added as an auxiliary stabilizing agent together with the locust bean gum in an amount less than 0.1% by weight based on the total weight of the finished product.

3. The method according to claim 2, wherein the auxiliary stabilizing agent is added in an amount of 0.03 to 0.06% by weight based on the total weight of the finished product.

4. The method according to claim 1, wherein the emulsion of whole milk containing locust bean gum is mixed with the acidifying agent at a temperature of 40° to 50° C. in step (2).

5. The method according to claim 1, wherein the acidified emulsion of whole milk is homogenized by passage through a Gauline homogenizer.

6. A stable, emulsified, acidified whole milk beverage free from segregated curds comprising whole milk, water, 0.3% by weight of locust bean gum, based on the total weight of the beverage, as a stabilizing agent, and an amount of at least one acidifying agent, selected from the group consisting of fruit juice and organic acids acceptable for use with beverages, sufficient to impart a pH of between 3.4 and 3.6 to said beverage.

7. The acidified milk beverage according to claim 6, wherein the fruit juice is at least one juice from a fruit selected from the group consisting of oranges, pineapples, apples, grapes, grapefruits, lemons, melons and strawberries.

8. The acidified milk beverage according to claim 7 or 6, wherein the organic acid is at least one selected from the group consisting of succinic acid, lactic acid, malic acid, tartaric acid, citric acid, gluconic acid and ascorbic acid.

9. The acidified milk beverage according to claim 6, which mainly consists of whole milk, fruit juice and organic acid.

10. The acidified milk beverage according to claim 6, whose saccharinity ranges from about 10° to 13° as measured by a saccharimeter.

11. A stable, emulsified, acidified whole milk beverage free from segregated curds consisting essentially of whole milk, water, fruit juice, an organic acid acceptable for use with a beverage, a sweetening agent, and 0.3% by weight of locust bean gum, as a stabilizer, based on the total weight of said beverage, said beverage containing sufficient fruit juice and organic acid to impart a pH of from 3.4 to 3.6 to said beverage.

12. The acidified milk beverage according to claim 6 or 11, which further contains less than 0.1% by weight of agar or pectin as an auxiliary stabilizing agent based on the total weight of the beverage.

13. The acidified milk beverage according to claim 12, which further contains 0.03 to 0.06% by weight of the auxiliary stabilizing agent based on the total weight of the beverage.

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